Department of Law and Public Safety
Division of Consumer Affairs
Board of Pharmacy
Statutes and Regulations

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TITLE 45. PROFESSIONS AND OCCUPATIONS

CHAPTER 1
GENERAL PROVISIONS

ARTICLE 1. GENERAL PROVISIONS RELATING TO ALL PROFESSIONS AND OCCUPATIONS AFFECTED BY THIS SUBTITLE

45:1-1. Persons entitled to practice, etc. under former laws unaffected

Any person now entitled to practice any profession or to engage in any occupation, governed or regulated by the provisions of this title by virtue of any prior law, shall continue to be entitled to practice or engage in the same, notwithstanding the enactment of this title, and the validity of any license or other authorization to practice any such profession or to engage in any such occupation, heretofore issued to any person under any prior law, or of any proceeding pending to obtain such a license or authorization shall not be affected by the enactment of this title but all such persons shall in all other respects be subject to the provisions of this title.

ARTICLE 2. GENERAL PROVISIONS RELATING TO CERTAIN STATE BOARDS OF REGISTRATION AND EXAMINATION

45:1-2. Repealed by L.1971, c. 60, § 5, eff. March 25, 1971

45:1-2.1. Professional boards and commissions; application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the New Jersey Real Estate Commission, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, and the State Board of Public Movers and Warehousemen.[1]

L.1971, c. 60, § 1, eff. March 25, 1971. Amended by L.1983, c. 7, § 19, eff. Jan. 18, 1983; L.1984, c. 205, § 40; L.1989, c. 153, § 22; L.1991, c. 31, § 16, eff. Aug. 20, 1991; L.1991, c. 68, § 27, eff. March 21, 1991; L.1991, c. 134, § 15, eff. May 6, 1991.

Amended by L.1993, c. 365, § 18, eff. Jan. 4, 1994; L.1995, c. 366, § 20, eff. Jan. 5, 1996.

[1] Abolition of State Board of Public Movers and Warehousemen and transfer of functions, powers and duties to the Division of consumer Affairs. See Reorganization Plan No. 008-1998, set out under § 45:14D-4.

45:1-2.2. Appointment of members by governor; public members; member from department in executive branch; quorum; vote necessary for action

a. All members of the several professional boards and commissions shall be appointed by the Governor in the manner prescribed by law; except in appointing members other than those appointed pursuant to subsection b. or subsection c., the Governor shall give due consideration to, but shall not be bound by, recommendations submitted by the appropriate professional organizations of this State.

b. In addition to the membership otherwise prescribed by law, the Governor shall appoint in the same manner as presently prescribed by law for the appointment of members, two additional members to represent the interests of the public, to be known as public members, to each of the following boards and commissions: The New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the New Jersey Real Estate Commission, the State Board of Shorthand Reporting, the State Board of Social Work Examiners, and the State Board of Veterinary Medical Examiners, and one additional public member to each of the following boards: the Board of Examiners of Electrical Contractors, the State Board of Marriage and Family Therapy Examiners, the State Board of Examiners of Master Plumbers, and the State Real Estate Appraiser Board. Each public member shall be appointed for the term prescribed for the other members of the board or commission and until the appointment of his successor. Vacancies shall be filled for the unexpired term only. The Governor may remove any such public member after hearing, for misconduct, incompetency, neglect of duty or for any other sufficient cause.

No public member appointed pursuant to this section shall have any association or relationship with the profession or a member thereof regulated by the board of which he is a member, where such association or relationship would prevent such public member from representing the interest of the public. Such a relationship includes a relationship with members of one's immediate family; and such association includes membership in the profession regulated by the board. To receive services rendered in a customary client relationship will not preclude a prospective public member from appointment. This paragraph shall not apply to individuals who are public members of boards on the effective date of this act.

It shall be the responsibility of the Attorney General to insure that no person with the aforementioned association or relationship or any other questionable or potential conflict of interest shall be appointed to serve as a public member of any board regulated by this section.

Where a board is required to examine the academic and professional credentials of an applicant for licensure or to test such applicant orally, no public member appointed pursuant to this section shall participate in such examination process; provided, however, that public members shall be given notice of and may be present at all such examination processes and deliberations concerning the results thereof, and, provided further, that public members may participate in the development and establishment of the procedures and criteria for such examination processes.

c. The Governor shall designate a department in the Executive Branch of the State Government which is closely related to the profession or occupation regulated by each of the boards or commissions designated in section 1 of P.L.1971, c. 60 (C. 45:1-2.1) and shall appoint the head of such department, or the holder of a designated office or

position in such department, to serve without compensation at the pleasure of the Governor as a member of such board or commission.

d. A majority of the voting members of such boards or commissions shall constitute a quorum thereof and no action of any such board or commission shall be taken except upon the affirmative vote of a majority of the members of the entire board or commission.

L.1971, c. 60, § 2, eff. March 25, 1971. Amended by L.1977, c. 285, § 1, eff. Nov. 12, 1977; L.1981, c. 295, § 14, eff. Oct. 9, 1981; L.1984, c. 205, § 41; L.1991, c. 68, § 28, eff. March 21, 1991; L.1991, c. 134, § 16, eff. May 6, 1991.

Amended by L.1995, c. 366, § 21, eff. Jan. 5, 1996.

45:1-2.3. Qualifications; rights and duties

Such additional members:

a. Need not meet the educational and professional requirements for membership on such boards or commissions as provided in the several statutes establishing such boards and commissions; and

b. Shall be voting members subject to the same rights, obligations and duties as other members of their respective boards or commissions.

L.1971, c. 60, § 3, eff. March 25, 1971.

45:1-2.4. Effect of act on term of member in office

Nothing in this act shall affect the right of a board or commission member in office on the effective date of this act to continue to serve for the term for which he was appointed.

L.1971, c. 60, § 4, eff. March 25, 1971.

41:1-2.5. Compensation and reimbursement of expenses of members; executive secretaries; compensation and terms of employment; offices and meeting places.

With respect to the boards or commissions designated in section 1 of P.L.1971, c. 60 (C.45:1-2.1), except as otherwise provided in subsection d. of this section, and notwithstanding the provisions of any other law:

a. The officers and members shall be compensated on a per diem basis in the amount of $25.00 or an amount to be determined by the Attorney General, with the approval of the State Treasurer, but not to exceed $100.00 per diem or $2,500.00 annually, and shall be reimbursed for actual expenses reasonably incurred in the performance of their official duties. Such moneys shall be paid according to rules and regulations promulgated by the Attorney General.

b. The executive secretary shall receive such salary as shall be determined by the appointing authority within the limits of available appropriations and shall serve at its pleasure. Any such executive secretary who holds a certificate, license or registration issued by the board or commission by which he is employed shall not during such employment be permitted to engage in any profession or occupation regulated by the board or commission.

c. The head of the department to which such board or commission is assigned shall maintain within any public building, whether owned or leased by the State, suitable quarters for the board's or commission's office and meeting place, provided that no such office or meeting place shall be within premises owned or occupied by an officer or member of such board or commission.

d. The compensation schedule for members of boards and commissions provided in subsection a. of this section shall not apply to the members of the New Jersey Real Estate Commission, who shall be compensated pursuant to R.S.45:15-6 or to members of the State Board of Medical Examiners who shall receive compensation of $150 per diem.

L.1977, c. 285, § 2. Amended by L.1981, c. 91, § 1, eff. March 31, 1981; L.1985, c. 137, § 2, eff. April 12, 1985; L.1989, c. 300, § 17, eff. Jan. 12, 1990.

45:1-2.6. Inapplicability of act to rights under civil service or any pension law or retirement system

Nothing in this act shall deprive any person of any tenure rights or of any right or protection provided him by Title 11 of the Revised Statutes, Civil Service,[1] or any pension law or retirement system.

L.1977, c. 285, § 3, eff. Nov. 12, 1977.

[1]Now title 11A.

45:1-3. Expenses of boards paid from income; surplus paid to state treasurer; accounts

Each member of the boards mentioned in section 45:1-2[1] of this title shall be entitled to his actual traveling and other expenses incurred in the performance of his duties, which sum shall be paid from the license fees and other sources of income of such boards. Such boards shall also be entitled to expend from their income such sums as shall be necessary to defray all proper expenses incurred by them in the performance of their duties, including the compensation of any of their officers or agents whom they are authorized to compensate. Such boards, if authorized to collect an annual registration or license fee from persons licensed by them, may retain in their treasuries the fees so collected and use the same for the purpose of defraying the expenses of securing evidence against and prosecuting persons violating the provisions of the laws with the enforcement of which they are charged, or, in case the revenue of the boards from other sources shall be insufficient to pay the salary of their secretaries and their other expenses, such fees may be expended for such purposes. Such boards shall be entitled to retain, in addition to the above, at least one hundred dollars in their treasuries for the purpose of preparing and holding their examinations. On or before October thirty-first in each year such boards shall pay to the state treasurer all moneys remaining in their treasuries, except as above stated, which sum, when so paid, shall form a part of the state fund. Such boards shall keep accurate accounts of their receipts and expenditures, which accounts shall be subject to audit by the state comptroller.

[1]Repealed; see, now, § 45:1-2.1, 45:1-2.2.

45:1-3.1. Application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling,

the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, and the State Board of Social Work Examiners.

L.1974, c. 46, § 1, eff. June 24, 1974. Amended by L.1983, c. 7, § 20, eff. Jan. 18, 1983; L.1984, c. 205, § 42; L.1989, c. 153, § 23; L.1991, c. 31, § 17, eff. Aug. 20, 1991; L.1991, c. 68, § 29, eff. March 21, 1991; L.1991, c. 134, § 17, eff. May 6, 1991.

Amended by L.1995, c. 366, § 22, eff. Jan. 5, 1996.

45:1-3.2. Charges for examinations, licensures and other services; establishment or change by rule; standards

Notwithstanding the provisions of Title 45 of the Revised Statutes or any other law to the contrary, any board or commission named in section 1 of this supplementary act[1] may by rule establish, prescribe or change the charges for examinations, licensures and other services it performs, which rule shall first be approved by the head of the department to which such board or commission is assigned and shall be adopted in accordance with the provisions of the "Administrative Procedure Act," P.L.1968, c. 410 (C. 52:14B-1).

Any board's or commission's charges established, prescribed or changed pursuant to this section shall be established, prescribed or changed to such extent as shall be necessary to defray all proper expenses incurred by the board or commission in the performance of its duties but such charges shall not be fixed at a level that will raise amounts in excess of the amount estimated to be so required.

L.1974, c. 46, § 2, eff. June 24, 1974.

[1] N.J.S.A. § 45:1-3.1.

45:1-3.3. Administrative fees charged by boards; modification

The Director of the Division of Consumer Affairs may by rule establish, prescribe, or modify administrative fees charged by boards in accordance with the "Administrative Procedure Act," P.L.1968, c. 410 (C.52:14B-1 et seq.). For purposes of this section, "administrative fees" are charges assessed to licensees, registrants or holders of certificates, as the case may be, for board functions that are not unique to a particular board but are uniform throughout all boards. Administrative fees include, but are not limited to, fees for a duplicate or replacement license, certification or registration, late renewal fee, license reinstatement fee, and the fee for processing change of address.

L.1999, c. 403, § 4, eff. Jan. 18, 2000.

45:1-4. Salary of secretary

The secretary of each of the boards mentioned in section 45:1-2 [1] of this title, whether or not a member thereof, shall be entitled to receive such reasonable salary or compensation for his services as secretary as shall be fixed by such boards, which shall be paid by the boards from their receipts, unless an appropriation is made for the expenses of such boards, in which case the same shall be paid from such appropriation.

[1] Repealed. See, now, § 45:1-2.1, 45:1-2.2.

45:1-5, 45:1-6. Repealed by L.1979, c. 432, § 4, eff. Feb. 14, 1980

45:1-7. Professional or occupational licenses or certificates of registration; duration; expiration; exceptions; fees

Notwithstanding any of the provisions of Title 45 of the Revised Statutes or of any other law to the contrary, all professional or occupational licenses or certificates of registration, except such licenses or certificates issued to real estate brokers or salesmen pursuant to chapter 15 of Title 45, which prior to the effective date of this act were issued for periods not exceeding one year and were annually renewable, shall, on and after the effective date of this act, be issued for periods of two years and be biennially renewable, except that licenses and business permits issued to electrical contractors and certificates of registration issued to qualified journeymen electricians pursuant to chapter 5A of Title 45 shall be issued for periods of three years and be triennially renewable; provided, however, the boards or commissions in charge of the issuance or renewal of such licenses or certificates may, in order to stagger the expiration dates thereof, provide that those first issued or renewed after the effective date of this act, shall expire and become void on a date fixed by the respective boards or commissions, not sooner than six months nor later than 29 months, after the date of issue.

The fees for the respective licenses and certificates of registration issued pursuant to this act for periods of less or greater than one year shall be in amounts proportionately less or greater than the fees established by law.

L.1972, c. 108, § 1. Amended by L.1991, c. 6, § 1.

Amended by L.2001, c. 21, § 1.

45:1-7.1. Application to holders of professional or occupational licenses

a. Notwithstanding any other act or regulation to the contrary, the provisions of this section and sections 6 and 7 of P.L.1999, c. 403 (C.45:1-7.2 et al.) shall apply to every holder of a professional or occupational license or certificate of registration or certification issued or renewed by a board specified in section 2 of P.L. 1978, c. 73 (C.45:1-15), who seeks renewal of that license or certificate.

b. Every holder of a professional or occupational license or certificate of registration or certification, issued or renewed by a board specified in section 2 of P.L.1978, c. 73 (C.45:1-15), who seeks renewal shall submit a renewal application and pay a renewal fee prior to the date of expiration of the license or certificate of registration or certification. If the holder does not renew the license or certificate prior to its expiration date, the holder may renew it within 30 days of its expiration date by submitting a renewal application and paying a renewal fee and a late fee. Any professional or occupational license or certificate of registration or certification not renewed within 30 days of its expiration date shall be suspended without a hearing.

c. Any individual who continues to practice with an expired license or certificate of registration or certification after 30 days following its expiration date shall be deemed to be engaged in unlicensed practice of the regulated profession or occupation, even if no notice of suspension has been provided to the individual.

d. A professional or occupational license or certificate of registration or certification suspended pursuant to this section may be reinstated within five years following its date of expiration upon submission of a renewal application and payment of an additional reinstatement fee. An applicant seeking reinstatement of a license or certificate suspended pursuant to this section more than five years past its expiration date shall successfully complete the examination required for initial licensure, registration or certification and submit a renewal application and payment of an additional reinstatement fee.

e. A board specified in section 2 of P.L. 1978, c. 73 (C. 45:1-15) shall send a notice of renewal to each of its holders of a professional or occupational license or certificate of registration or certification, as applicable, at least 60 days prior to the expiration of the license or certificate. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

L.1999, c. 403, § 5, eff. Jan. 18, 2000.

45:1-7.2. Reinstatement

A board may reinstate the professional or occupational license or certificate of registration or certification of an applicant whose license or certificate has been suspended pursuant to section 5 of P.L.1999, c. 403 (C.45:1-7.1), provided that the applicant otherwise qualifies for licensure, registration or certification and submits the following upon application for reinstatement:

a. Payment of all past delinquent renewal fees;

b. Payment of a reinstatement fee;

c. An affidavit of employment listing each job held during the period of suspended license, registration or certification which includes the names, addresses, and telephone numbers of each employer; and

d. If applicable, satisfactory proof that the applicant has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license or certificate of registration or certification.

L.1999, c. 403, § 6, eff. Jan. 18, 2000.

45:1-7.3. Renewal applications

a. Renewal applications for all professional or occupational licenses or certificates of registration or certification shall provide the applicant with the option of either active or inactive renewal. A renewal applicant electing to renew as inactive shall not engage in professional or occupational practice within the State.

b. An applicant who selects the inactive renewal option shall remain on inactive status for the entire renewal period unless, upon application to the board, the board permits the inactive applicant to return to active status provided such applicant presents satisfactory proof that he has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license, registration or certification, if applicable.

L.1999, c. 403, § 7, eff. Jan. 18, 2000.

45:1-8. Contractors; application of § 45:1-9

The provisions of this act apply to the following classes of contractors:

a. Tree experts, certified pursuant to P.L.1940, c. 100 (C. 13:1-28 et seq.[1]);

b. Home repair contractors, licensed pursuant to P.L.1960, c. 41 (C. 17:16C-62 et seq.);

c. Electrical contractors, licensed pursuant to P.L.1962, c. 162 (C. 45:5A-1 et seq.);

d. Master plumbers, licensed pursuant to P.L.1968, c. 362 (C. 45:14C-1 et seq.);

e. Well drillers, licensed pursuant to P.L.1947, c. 377 (C. 58:4A-5 et seq.); and

f. Any class of contractors who hereafter are licensed by the State.

L.1973, c. 254, § 1, eff. Nov. 26, 1973.

[1]Renumbered C. 45:15C-1 to 45:15C-10.

45:1-9. Indication of license or certificate number on contracts, bids and advertisements

Any contractor licensed by the State shall indicate his license or certificate number on all contracts, subcontracts, bids and all forms of advertising as a contractor.

L.1973, c. 254, § 2, eff. Nov. 26, 1973.

45:1-10. Disclosure of laboratory payments on bills to patients and third party payors

It shall be unlawful for any person licensed in the State of New Jersey to practice medicine or surgery, dentistry, osteopathy, podiatry or chiropractic to agree with any clinical, bio-analytical or hospital laboratory, wheresoever located, to make payments to such laboratory for individual tests, combination of tests, or test series for patients unless such person discloses on the bills to patients and third party payors the name and address of such laboratory and the net amount or amounts paid or to be paid to such laboratory for individual tests, combination of tests or test series.

L.1973, c. 322, § 1, eff. Dec. 18, 1973. Amended by L.1977, c. 323, § 1, eff. Jan. 10, 1978.

45:1-10.1. Claims for third party payment; licensed health care professional; responsibility for filing

Effective 12 months after the adoption of regulations establishing standard health care enrollment and claim forms by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23), a health care professional licensed pursuant to Title 45 of the Revised Statutes is responsible for filing all claims for third

party payment, including claims filed on behalf of the licensed professional's patient for any health care service provided by the licensed professional that is eligible for third party payment, except that at the patient's option, the patient may file the claim for third party payment.

a. In the case of a claim filed on behalf of the professional's patient, the professional shall file the claim within 60 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23).

b. In the case of a claim in which the patient has assigned his benefits to the professional, the professional shall file the claim within 180 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23). If the professional does not file the claim within 180 days of the last date of service for a course of treatment, the third party payer shall reserve the right to deny payment of the claim, in accordance with regulations established by the Commissioner of Banking and Insurance, and the professional shall be prohibited from seeking any payment directly from the patient.

(1) In establishing the standards for denial of payment, the Commissioner of Banking and Insurance shall consider the good faith use of information provided by the patient to the professional with respect to the identity of the patient's third party payer, delays in filing a claim related to coordination of benefits between third party payers and any other factors the commissioner deems appropriate, and, accordingly, shall define specific instances where the sanctions permitted pursuant to this subsection shall not apply.

(2) A professional who fails to file a claim within 180 days and whose claim for payment has been denied by the third party payer in accordance with this subsection may, in the discretion of a judge of the Superior Court, be permitted to refile the claim if the third party payer has not been substantially prejudiced thereby. Application to the court for permission to refile a claim shall be made within 14 days of notification of denial of payment and shall be made upon motion based upon affidavits showing sufficient reasons for the failure to file the claim with the third party payer within 180 days.

c. The provisions of this section shall not apply to any claims filed pursuant to P.L.1972, c. 70 (C.39:6A-1 et seq.).

d. A health care professional who violates the provisions of subsection a. of this section may be subject to a civil penalty of $250 for each violation plus $50 for each day after the 60th day that the provider fails to submit a claim. The penalty shall be sued for and collected by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to "the penalty enforcement law,''

N.J.S.A. 2A:58-1 et seq.

L.1999, c. 154, § 13, eff. July 1, 1999.

45:1-11. Violations; penalty

Any person violating this act shall be guilty of a misdemeanor.

L.1973, c. 322, § 2, eff. Dec. 18, 1973.

45:1-12. Podiatrist, optometrist or psychologist or professional service corporation; charge for completion of claim form for health insurance; fine; collection and enforcement

No podiatrist, optometrist or psychologist and no professional service corporation engaging in the practice of podiatry, optometry or psychology in this State shall charge a patient an extra fee for services rendered in completing a medical claim form in connection with a health insurance policy. Any person violating this act shall be subject to a fine of $100.00 for each offense.

Such penalty shall be collected and enforced by summary proceedings pursuant to the Penalty Enforcement Law (N.J.S. 2A:58-1 et seq.). The Superior Court and municipal court shall have jurisdiction within its territory of such proceedings. Process shall be either in the nature of a summons or warrant and shall issue in the name of the State, upon the complaint of the State Board of Medical Examiners with respect to podiatrists, the New Jersey State Board of Optometry for optometrists or the State Board of Psychological Examiners for psychologists.

L.1975, c. 300, § 1, eff. Jan. 30, 1976. Amended by L.1991, c. 91, § 447, eff. April 9, 1991.

45:1-13. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:1-14. Legislative findings and declarations; liberal construction of act

The Legislature finds and declares that effective implementation of consumer protection laws and the administration of laws pertaining to the professional and occupational boards located within the Division of Consumer Affairs require uniform investigative and enforcement powers and procedures and uniform standards for license revocation, suspension and other disciplinary proceedings by such boards. This act is deemed remedial, and the provisions hereof should be afforded a liberal construction.

L.1978, c. 73, § 1, eff. July 13, 1978.

45:1-15. Boards and professions or occupations regulated by or through such boards; application of act

The provisions of this act shall apply to the following boards and all professions or occupations regulated by, through or with the advice of those boards: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, the State Board of Physical Therapy, the Professional Counselor Examiners Committee, the New Jersey Cemetery Board, the Orthotics and Prosthetics Board of Examiners, the Occupational Therapy Advisory Council, the Electrologists Advisory Committee, the Alcohol and Drug Counselor Committee, the Fire Alarm, Burglar Alarm, and Locksmith Advisory Committee, the Home Inspection Advisory Committee, the Massage, Bodywork and Somatic Therapy Examining Committee, and the Audiology and Speech-Language Pathology Advisory Committee.

L.1978, c. 73, § 2, eff. July 13, 1978. Amended by L.1983, c. 7, § 21, eff. Jan. 18, 1983; L.1984, c. 205, § 43; L.1989, c. 153, § 24; L.1991, c. 31, § 18, eff. Aug. 20, 1991; L.1991, c. 68, § 30, eff. March 21, 1991; L.1991, c. 134, § 14, eff. May 6, 1991.

Amended by L.1995, c. 366, § 23, eff. Jan. 5, 1996; L.1999, c. 403, § 1, eff. Jan. 18, 2000.

45:1-15.1. Rules and regulations

Consistent with their enabling acts, P.L.1978, c. 73 (C.45:1-14 et seq.) and the "Administrative Procedure Act,'' P.L.1968, c . 410 (C.52:14B-1 et seq.), the boards and others set forth in section 2 of P .L.1978, c. 73 (C.45:1-15) are authorized to adopt rules and regulations to serve the public health, safety and welfare.

L.1999, c. 403, § 8, eff. Jan. 18, 2000.

45:1-16. Definitions

As used within this act the following words or terms shall have the indicated definition unless the context clearly indicates otherwise.

"Board'' means any professional or occupational licensing board designated in section 2 of this act.[1]

"Director'' means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Person'' means any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trust thereof.

L.1978, c. 73, § 3, eff. July 13, 1978.

[1]N.J.S.A. § 45:1-15.

45:1-17. Powers of Attorney General to implement act and administer law enforcement activities of boards

In implementing the provisions of this act and administering the law enforcement activities of those professional and occupational boards located within the Division of Consumer Affairs, the Attorney General may:

a. After advice to the board or boards in question of his intent to proceed under this section, and the specific action he intends to take, and the failure of such board or boards to take steps in accordance with the advice of the Attorney General within 30 days of receipt of such advice, promulgate rules and regulations consistent with the provisions of this act and the Administrative Procedure Act, P.L.1968, c. 410 (C. 52:14B-1 et seq.) governing the procedure for administrative hearings before all boards within the Division of Consumer Affairs. Such rules and regulations shall govern administrative complaints, answers thereto, issuance of subpenas, appointment of hearing examiners, adjournments, submission of proposed findings of fact and conclusions of law, the filing of briefs, and such other procedural aspects of administrative hearings before the boards as the Attorney General may deem necessary; provided, however, nothing herein authorized shall be construed to require the Attorney General to promulgate rules regarding prehearing investigative procedures.

b. After advice to the board or boards in question of his intent to proceed under this section, and the specific action he intends to take, and the failure of such board or boards to take steps in accordance with the advice of the Attorney General within 30 days of receipt of such advice, promulgate substantive rules and regulations consistent with the provisions of any statute governing the activities of any licensing agency, board or committee located within the Division of Consumer Affairs, which shall be limited to disciplinary matters and arbitrary restrictions on initial licensure. In addition to promulgating such rules and regulations, the Attorney General may direct that any proposed or existing regulation be amended, abandoned or repealed. Prior to the final adoption of any regulation affecting the activities of any professional or occupational licensing agency, board or committee located within the division and prior to the issuance of any directive to amend, abandon or repeal any regulation, the Attorney General or his designee shall first consult with the agency, board or committee whose activities are affected regarding the proposed action.

c. After a full consideration of all relevant facts and the applicable law, may direct the initiation of any appropriate enforcement action by a professional or occupational licensing board or set aside, modify or amend, as may be necessary, any action or decision of a licensing agency, board or committee located within the Division of Consumer Affairs; provided, however, no such action shall be directed by the Attorney General in reviewing the action or decision of an agency, board or committee unless such action or decision is contrary to applicable law.

L.1978, c. 73, § 4, eff. July 13, 1978.

45:1-18. Investigative powers of boards, director or attorney general

Whenever it shall appear to any board, the director or the Attorney General that a person has engaged in, or is engaging in any act or practice declared unlawful by a statute or regulation administered by such board, or when the board, the director or the Attorney General shall deem it to be in the public interest to inquire whether any such violation may exist, the board or the director through the Attorney General, or the Attorney General acting independently, may exercise any of the following investigative powers:

a. Require any person to file on such form as may be prescribed, a statement or report in writing under oath, or otherwise, as to the facts and circumstances concerning the rendition of any service or conduct of any sale incidental to the discharge of any act or practice subject to an act or regulation administered by the board;

b. Examine under oath any person in connection with any act or practice subject to an act or regulation administered by the board;

c. Inspect any premises from which a practice or activity subject to an act or regulation administered by the board is conducted;

d. Examine any goods, ware or item used in the rendition of a practice or activity subject to an act or regulation administered by the board;

e. Examine any record, book, document, account or paper prepared or maintained by or for any professional or occupational licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in practices subject to an act or regulation administered by the board. Nothing in this subsection shall require the notification or consent of the person to whom the record, book, account or paper pertains, unless otherwise required by law;

f. For the purpose of preserving evidence of an unlawful act or practice, pursuant to an order of the Superior Court, impound any record, book, document, account, paper, goods, ware, or item used, prepared or maintained by or for any board licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in a practice or activity subject to an act or regulation administered by the board. In such cases as may be necessary, the Superior Court may, on application of the Attorney General, issue an order sealing items or material subject to this subsection; and

g. Require any board licensee, permit holder or registered or certified person to submit to an assessment of skills to determine whether the board licensee, permit holder or registered or certified person can continue to practice with reasonable skill and safety.

In order to accomplish the objectives of this act or any act or regulation administered by a board, the Attorney General may hold such investigative hearings as may be necessary and the board, director or Attorney General may issue subpoenas to compel the attendance of any person or the production of books, records or papers at any such hearing or inquiry.

L.1978, c. 73, § 5, eff. July 13, 1978.

Amended by L.2001, c. 307, § 1, eff. Jan. 3, 2002.

45:1-19. Failure or refusal to file statement or report, refusal of access to premises or failure to obey subpena; penalty

If any person shall fail or refuse to file any statement or report or refuse access to premises from which a licensed profession or occupation is conducted in any lawfully conducted investigative matter or fail to obey a subpena issued pursuant to this act, the Attorney General may apply to the Superior Court and obtain an order:

a. Adjudging such person in contempt of court; or

b. Granting such other relief as may be required; or

c. Suspending the license of any such person unless and until compliance with the subpena or investigative demand is effected.

L.1978, c. 73, § 6, eff. July 13, 1978.

45:1-20. Compelling testimony or production of book, paper or document; immunity from prosecution

If any person shall refuse to testify or produce any book, paper, or other document in any proceeding under this act for the reason that the testimony or evidence, documentary or otherwise, required of him may tend to incriminate him, convict him of a crime, or subject him to a penalty or forfeiture, and shall, notwithstanding, be directed to testify or to produce such book, paper, or document by the Attorney General, he shall comply with such direction.

A person who is entitled by law to, and does assert such privilege, and who complies with such direction of the Attorney General shall not thereafter be prosecuted or subjected to any penalty or forfeiture in any criminal proceeding which arises out of and relates to the subject matter of the proceeding. No person so testifying shall be

exempt from prosecution or punishment for perjury or false swearing committed by him in giving such testimony or from any civil or administrative action arising from such testimony.

L.1978, c. 73, § 7, eff. July 13, 1978.

45:1-21. Grounds for refusal to admit to examination or denial, suspension or revocation of any certificate, registration or license; definitions

A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or misrepresentation;

b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

d. Has engaged in repeated acts of negligence, malpractice or incompetence;

e. Has engaged in professional or occupational misconduct as may be determined by the board;

f. Has been convicted of, or engaged in acts constituting, any crime or offense involving moral turpitude or relating adversely to the activity regulated by the board. For the purpose of this subsection a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, agency or authority for reasons consistent with this section;

h. Has violated or failed to comply with the provisions of any act or regulation administered by the board;

i. Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;

j. Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with, such applications, required to be filed with the Department of Environmental Protection;

k. Has violated any provision of P.L.1983, c. 320 (C.17:33A-1 et seq.) or any insurance fraud prevention law or act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L.1983, c. 320 (C.17:33A-1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under that act against the applicant or holder;

l. Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subsection, the term " "presently'' means at this time or any time within the previous 365 days;

m. Has prescribed or dispensed controlled dangerous substances indiscriminately or without good cause, or where the applicant or holder knew or should have known that the substances were to be used for unauthorized consumption or distribution;

n. Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the board, or aided and abetted an unlicensed person or entity in performing such an act;

o. Advertised fraudulently in any manner.

For purposes of this act:

"Completed application'' means the submission of all of the information designated on the checklist, adopted pursuant to section 1 of P.L.1991, c. 421 (C.13:1D-101), for the class or category of permit for which application is made.

"Permit'' has the same meaning as defined in section 1 of P.L.1991, c. 421 (C.13:1D-101).

L.1978, c. 73, § 8, eff. July 13, 1978.

Amended by L.1991, c. 420, § 1, eff. May 16, 1992; L.1997, c. 151, § 10, eff. June 30, 1997; L.1999, c. 403, § 2, eff. Jan. 18, 2000.

45:1-21.1. Annual summary of compliance information and attendance at continuing education seminars; costs; information deemed public records

a. A board obtaining information from the Department of Environmental Protection pursuant to section 1 of P.L.1991, c. 418 (C. 13:1D-110) on the compliance of a member of a regulated profession with the requirements for completed applications of the department, shall annually develop a detailed written summary of the information gathered by the department pursuant to P.L.1991, c. 418 (C. 13:1D-110) regarding compliance with the department's requirements for completed applications and attendance records for continuing education seminars required to be filed with the department pursuant to section 2 of P.L.1991, c. 419 (C. 13:1D-117).

b. Any reasonable costs incurred in preparation of the report required pursuant to this section may be included in the charges authorized pursuant to P.L.1974, c. 46 (C. 45:1-3.2).

c. Information required to be compiled by a board pursuant to this section, shall be deemed to be public records subject to the requirements of P.L.1963, c. 73 (C. 47:1A-1 et seq.).

L.1991, c. 420, § 2, eff. May 16, 1992.

45:1-21.2. Suspension of certain licenses; hearing

The director or a board shall suspend, as appropriate, after a hearing, the license, registration or certification of any person who has been certified by a lender or guarantor and reported to the director or the board, as the case may be, for nonpayment or default of a State or federal direct or guaranteed educational loan. The license, registration or certification shall not be reissued until the person provides the director or board with a written release issued by the lender or guarantor stating that the person has cured the default or is making payments on the loan in accordance with a repayment agreement approved by the lender or guarantor. If the person has continued to meet all other requirements for licensure, registration or certification during the suspension, reinstatement shall be automatic upon receipt of the notice and payment of any reinstatement fee the director or the board may impose.

L.1999, c. 54, § 1.

45:1-22. Additional or alternative penalties to revocation, suspension or refusal to renew; temporary order suspending or limiting license; subpena

In addition or as an alternative, as the case may be, to revoking, suspending or refusing to renew any license, registration or certificate issued by it, a board may, after affording an opportunity to be heard:

a. Issue a letter of warning, reprimand, or censure with regard to any act, conduct or practice which in the judgment of the board upon consideration of all relevant facts and circumstances does not warrant the initiation of formal action;

b. Assess civil penalties in accordance with this act;

c. Order that any person violating any provision of an act or regulation administered by such board to cease and desist from future violations thereof or to take such affirmative corrective action as may be necessary with regard to any act or practice found unlawful by the board;

d. Order any person found to have violated any provision of an act or regulation administered by such board to restore to any person aggrieved by an unlawful act or practice, any moneys or property, real or personal, acquired by means of such act or practice; provided, however, no board shall order restoration in a dollar amount greater than those moneys received by a licensee or his agent or any other person violating the act or regulation administered by the board;

e. Order any person, as a condition for continued, reinstated or renewed licensure, to secure medical or such other professional treatment as may be necessary to properly discharge licensee functions;

f. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to any medical or diagnostic testing and monitoring or psychological evaluation which may be required to evaluate whether continued practice may jeopardize the safety and welfare of the public;

g. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to take and successfully complete educational training determined by the board to be necessary;

h. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to submit to any supervision, monitoring or limitation on practice determined by the board to be necessary.

A board may, upon a duly verified application of the Attorney General that either provides proof of a conviction of a court of competent jurisdiction for a crime or offense involving moral turpitude or relating adversely to the regulated profession or occupation, or alleges an act or practice violating any provision of an act or regulation administered by such board, enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint; provided, however, no such temporary order shall be entered unless the application made to the board palpably demonstrates a clear and imminent danger to the public health, safety and welfare and notice of such application is given to the licensee affected by such order. If, upon review of the Attorney General's application, the board determines that, although no palpable demonstration of a clear and imminent danger has been made, the licensee's continued unrestricted practice pending plenary hearing may pose a risk to the public health, safety and welfare, the board may order the licensee to submit to medical or diagnostic testing and monitoring, or psychological evaluation, or an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety.

In any administrative proceeding commenced on a complaint alleging a violation of an act or regulation administered by a board, such board may issue subpoenas to compel the attendance of witnesses or the production of books, records, or documents at the hearing on the complaint.

L.1978, c. 73, § 9, eff. July 13, 1978.

Amended by L.1999, c. 403, § 3, eff. Jan. 18, 2000; L.2001, c. 307, § 2, eff. Jan. 3, 2002.

45:1-23. Summary proceeding in Superior Court; injunction; orders necessary to prevent unlawful practice or remedy past unlawful activity

Whenever it shall appear to a board, the director or the Attorney General that a violation of any act, including the unlicensed practice of the regulated profession or occupation, or regulation administered by such board has occurred, is occurring, or will occur, the Attorney General, in addition to any other proceeding authorized by law, may seek and obtain in a summary proceeding in the Superior Court an injunction prohibiting such act or practice. In any such proceeding the court may assess a civil penalty in accordance with the provisions of this act, order restoration to any person in interest of any moneys or property, real or personal, acquired by means of an unlawful act or practice and may enter such orders as may be necessary to prevent the performance of an unlawful practice in the future and to fully remedy any past unlawful activity. In any action brought pursuant to this section, the court shall not suspend or revoke any license issued by a board.

L.1978, c. 73, § 10, eff. July 13, 1978.

45:1-24. Failure to comply with order of board directing payment of penalties or restoration of moneys or property; enforcement

Upon the failure of any person to comply within 10 days after service of any order of a board directing payment of penalties or restoration of moneys or property, the Attorney General or the secretary of such board may issue a certificate to the Clerk of the Superior Court that such person is indebted to the State for the payment of such penalty and the moneys or property ordered restored. A copy of such certificate shall be served upon the person against whom the order was entered. Thereupon the clerk shall immediately enter upon his record of docketed judgments the name of the person so indebted and of the State, a designation of the statute under which the penalty is imposed, the amount of the penalty imposed, and amount of moneys ordered restored, a listing of property

ordered restored, and the date of the certification. Such entry shall have the same force and effect as the entry of a docketed judgment in the Superior Court, and the Attorney General shall have all rights and remedies of a judgment creditor in addition to exercising any other available remedies. Such entry, however, shall be without prejudice to the right of appeal to the Appellate Division of the Superior Court from the board's order.

An action to enforce the provisions of any order entered by a board or to collect any penalty levied thereby may be brought in any municipal court or the Superior Court in summary manner pursuant to the Penalty Enforcement Act, (N.J.S. 2A:58-1 et seq.) and the rules of court governing the collection of civil penalties. Process in such action shall be by summons or warrant, and in the event that the defendant fails to answer such action, the court shall issue a warrant for the defendant's arrest for the purpose of bringing such person before the court to satisfy any order entered.

L.1978, c. 73, § 11, eff. July 13, 1978. Amended by L.1991, c. 91, § 448,
eff. April 9, 1991.

45:1-25. Violations; civil penalty; action to collect or enforce

a. Any person who engages in any conduct in violation of any provision of an act or regulation administered by a board shall, in addition to any other sanctions provided herein, be liable to a civil penalty of not more than $10,000 for the first violation and not more than $20,000 for the second and each subsequent violation. For the purpose of construing this section, each act in violation of any provision of an act or regulation administered by a board shall constitute a separate violation and shall be deemed a second or subsequent violation under the following circumstances:

(1) an administrative or court order has been entered in a prior, separate and independent proceeding;

(2) the person is found within a single proceeding to have committed more than one violation of any provision of an act or regulation administered by a board; or

(3) the person is found within a single proceeding to have committed separate violations of any provision of more than one act or regulation administered by a board.

b. In lieu of an administrative proceeding or an action in the Superior Court, the Attorney General may bring an action in the name of any board for the collection or enforcement of civil penalties for the violation of any provision of an act or regulation administered by such board. Such action may be brought in summary manner pursuant to the "Penalty Enforcement Law of 1999,'' P.L.1999, c. 274 (C.2A:58-10 et seq.) and the rules of court governing actions for the collection of civil penalties in the municipal court where the offense occurred. Process in such action may be by summons or warrant and in the event that the defendant in such action fails to answer such action, the court shall, upon finding an unlawful act or practice to have been committed by the defendant, issue a warrant for the defendant's arrest in order to bring such person before the court to satisfy the civil penalties imposed. In any action commenced pursuant to this section, the court may order restored to any person in interest any moneys or property acquired by means of an unlawful act or practice.

c. Any action alleging the unlicensed practice of a profession or occupation shall be brought pursuant to this section or, where injunctive relief is sought, by an action commenced in the Superior Court.

d. In any action brought pursuant to this act, a board or the court may order the payment of costs for the use of the State, including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs.

L.1978, c. 73, § 12, eff. July 13, 1978. Amended by L.1991, c. 91, § 449, eff. April 9, 1991.

Amended by L.1999, c. 403, § 9, eff. Jan. 18, 2000; L.2001, c. 307, § 3, eff. Jan. 3, 2002.

45:1-26. Repeal of inconsistent acts and parts of acts

All acts and parts of acts inconsistent with this act are hereby superseded and repealed.

L.1978, c. 73, § 13, eff. July 13, 1978.

45:1-27. Severability

If any provision of this law or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the law which can be given effect without the invalid provision or application, and to this end the provisions of this law are severable.

L.1978, c. 73, § 14, eff. July 13, 1978.

BOARD OF PHARMACY

CHAPTER 14
NURSING

45:14-1. Board of pharmacy of the state of New Jersey; membership; appointment; term of office

The board of pharmacy of the State of New Jersey, hereinafter in this chapter designated as the "board'', established by an act entitled "An act to regulate the practice of pharmacy in this State,'' approved March nineteenth, one thousand nine hundred and one (L.1901, c. 51, p. 85), as amended and supplemented, is continued. The board shall consist of nine members, two of whom shall be public members and one of whom shall be a State executive department member appointed pursuant to the provisions of P.L.1971, c. 60 (C. 45:1-2.1 et seq.). Each of the remaining six members shall be appointed from time to time as hereinafter directed by the Governor, shall be a citizen of and an able and skilled registered pharmacist in this State, shall have been registered as a pharmacist in this State for at least five years prior to his appointment, shall be actually engaged either in conducting or directly supervising a pharmacy at the time of his appointment and shall continue in the practice of pharmacy during the term of his office. No member shall be a teacher or instructor in any college of pharmacy. Upon the expiration of the term of office of a member, his successor shall be appointed by the Governor for a term of five years from June first of the year in which the term of such former member expired, and the terms of not more than two members who are registered pharmacists shall expire in any year. Any vacancy in the membership of the board shall be filled for the unexpired term in the manner provided for an original appointment; and the New Jersey Pharmaceutical Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners Association, and the New Jersey Society of Hospital Pharmacists may each annually send to the Governor the names of four registered pharmacists engaged in the practice of pharmacy in this State and having the qualifications required by this section, one of whom the Governor may appoint to fill any vacancy occurring in the board.

In appointing members to the board to fill vacancies of members who are eligible to practice pharmacy, the Governor shall appoint members in such a manner so that the membership of the board includes at all times at least one pharmacist who represents a chain drug retailer, one pharmacist who works in a hospital, and one pharmacist who owns a pharmacy.

As used in this section, "chain drug retailer'' means a corporation which operates seven or more retail pharmacies, drugstores or pharmacy departments under a common trade name.

Amended by L.1985, c. 89, § 1, eff. March 26, 1985; L.1994, c. 166, § 1, eff. Dec. 20, 1994.

45:14-2. Oath of office; removals; quorum

Each person so appointed shall, within thirty days after his appointment, take and subscribe an oath, before an officer authorized to administer oaths in this state, that he will faithfully discharge the duties prescribed by this chapter, and file the same, within sixty days after his appointment, in the office of the secretary of state, and in default thereof the governor may, in the manner above prescribed, fill such vacancy caused by such failure to take and file said oath. The governor may remove a member of the board upon proven charges of inefficiency, incompetency, immorality or professional misconduct. Three members of the board shall constitute a quorum.

45:14-3. Officers of board; by-laws and rules; meetings; examinations; general powers and duties of board

The board shall elect a president, a secretary who may or may not be a member of the board, and a treasurer, and may make by-laws and rules for the proper fulfillment of its duties under this chapter. It shall meet on the third Thursday of January, April, July and October, in the city of Trenton, and at such other times and places as may be required. It shall examine into all applications for registration, and grant certificates of registration to all persons whom it shall judge on examination to be properly qualified to practice pharmacy. The examination shall include the subjects of materia medica, pharmacy, chemistry and toxicology. It shall keep a book of registration in which shall be entered the names and places of business of all persons registered under this chapter, and also a book of record of all its official transactions, which books shall be legal evidence of such transactions in any court of law. It may examine into all cases of alleged violations of this chapter and shall cause the prosecution of all persons not complying therewith; and it shall annually report to the governor and to the New Jersey Pharmaceutical Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners Association, and the New Jersey Society of Hospital Pharmacists, on or before the first day of November in each year, upon the condition of pharmacy in the state, which report shall embrace a detailed statement of the receipts and expenditures of the board.

Amended by L.1994, c. 166, § 2, eff. Dec. 20, 1994.

45:14-3.1. Schedule of fees

The following shall be the fees charged by the State board:

Examinations ..... $ 35.00
Reciprocity 50.00
Registered pharmacist renewal..... 15.00
Duplicate registered pharmacist renewal..... 5.00
Registered pharmacist renewal—for each lapsed year
Year ....5.00 per year
Certification of records..... 5.00
New pharmacy 100.00
Transfer of ownership 50.00
Change of location 100.00
Permit renewal..... 25.00
Duplicate permit renewal 5.00
Duplicate original certificate 10.00
Addition of name to certificate 5.00
Red book 3.00
Pharmacy permit holder 3.00
Reinstatement after 5 years 20.00

L.1970, c. 331, § 6, eff. Dec. 29, 1970.

45:14-3.2. Provision of list of pharmacy owners; updating of information

The Board of Pharmacy of the State of New Jersey shall provide to the State Board of Medical Examiners, the New Jersey State Board of Dentistry and the State Board of Veterinary Medical Examiners, upon request, a list of names

and addresses of all pharmacy owners in the State for use by the respective boards pursuant to P.L.1991, c. 304 (C. 45:9-16.1). The board shall periodically update the list and provide the updated information to the respective boards, as appropriate.

L.1991, c. 304, § 4, eff. Nov. 7, 1991.

45:14-4. Expenses and compensation of members and secretary; disposition of moneys collected

The members of the board shall receive all traveling and other necessary expenses incurred in the performance of their duties. The secretary of the board shall receive compensation for his services, to be fixed by the board. Each member of the board, other than the secretary, shall receive, in addition to such traveling and other necessary expenses the sum of ten dollars for each and every day upon which he is engaged upon the duties of the board. All money collected by the board from fees, penalties or otherwise, except such as shall be retained for traveling and other necessary expenses and for the compensation of the secretary and the per diem compensation for members as above provided, shall be paid into the state treasury on or before the tenth day of the month following the month in which such moneys are collected, but the board may retain, in addition to the sums above-mentioned, at least five hundred dollars in the treasury for the purpose of making investigations and preparing and holding examinations of applicants for license to practice said profession.

45:14-5. Repealed by L.1979, c. 432, § 3, eff. Feb. 14, 1980

45:14-6. Registration of pharmacists required; apprentices

No person, not a registered pharmacist within the meaning of this chapter, shall conduct any store or pharmacy, or employ any unregistered pharmacist or unregistered assistant for retailing, dispensing or compounding drugs, medicines or poisons, and no person not a registered pharmacist or a registered assistant, shall prepare and dispense physicians' prescriptions, or retail or dispense medicines or poisons, except under the immediate supervision of a registered pharmacist. This section shall not be so construed as to prohibit the employment of apprentices in pharmacies or drug stores, but they or other unregistered employees shall not be allowed to prepare, compound and dispense prescriptions, or to sell or furnish medicines, prescriptions or poisons, except in the presence of and under the personal supervision of a registered pharmacist of this state, who must either be the proprietor or owner of said store or pharmacy, or in the actual employ of such proprietor or owner. For the violation of this section the owner or proprietor of said store or pharmacy shall be equally liable as principal.

45:14-7. Qualifications of applicants; examination; fee; issuance of certificate

Every applicant for registration as a pharmacist under this chapter shall be not less than 21 years of age when completing all requirements for examination, shall be a citizen of the United States, or shall have declared his intention to become such citizen, shall be of good moral character, and not a chronic or persistent inebriate, and not addicted to the use of any narcotic or other habit-forming drug, shall have had such practical experience under the supervision of a registered pharmacist as is prescribed by the rules and regulations of the board, shall have been duly graduated or have met all of the requirements for graduation from a pharmacy course given in a school or college of pharmacy approved by the board and complying with the rules and regulations of the board. Each applicant shall before examination, pay to the secretary of the board the required fee, and upon passing an examination satisfactory to the board shall receive from the board a certificate of registration to practice pharmacy in the State.

The board is hereby authorized to conduct written examinations in the theoretical subjects for applicants for registration at any time after applicants have been certified as having fully completed all requirements for graduation by the registrar of a school or college of pharmacy approved by the board. No candidate shall be examined in practical pharmacy and laboratory work until he has met all of the requirements for registration provided in the law and rules of the board. Successful passing of the examination in theoretical subjects shall confer no rights or privileges upon the applicant in connection with the practice of pharmacy in this State.

Amended by L.1939, c. 85, p. 169, § 1, eff. June 6, 1939; L.1951, c. 225, p. 794, § 1, eff. June 13, 1951; L.1970, c. 331, § 1, eff. Dec. 29, 1970.

45:14-7.2. Veterans; credit for time in military or naval service

Any applicant for the registered pharmacist examinations in this State who subsequent to September 16, 1940, entered the active military or naval service of the United States, including any member of the American Merchant Marine during World War II who is declared by the United States Department of Defense to be eligible for federal veterans' benefits, and who, at the time of such entry, was a graduate of a pharmacy course given in an approved school or college of pharmacy, shall be given credit against the requirement of one year of practical experience, subsequent to graduation, for such time served in the active military or naval service of the United States or as a member of the American Merchant Marine upon presentation of proof of his discharge or release from such service under conditions other than dishonorable; provided, however, that such applicant completes all of the other requirements for registration as provided for under section 45:14-7 of the Revised Statutes, including the passing of the written examinations in the theoretical subjects, and presents himself or herself for the examination in practical pharmacy and laboratory work within a period of two years subsequent to the date of such discharge or release from such military or naval service or such declaration of eligibility for federal veterans' benefits by the Department of Defense. The board may make such rules and regulations as may be necessary therefor.

L.1946, c. 177, p. 764, § 1, eff. April 26, 1946. Amended by L.1991, c. 389,
§ 32, eff. Jan. 14, 1992.

45:14-7.3. Registered assistant pharmacist may become registered pharmacist; examination

Any registered assistant pharmacist of the State of New Jersey in good standing shall be granted, upon filing an application and the payment of a fee of twenty-five dollars ($25.00) at least fifteen days before each examination taken by him to the secretary of the board, an opportunity or opportunities but not more than three, within two years of the effective date of this act, to take an examination in practical pharmacy and laboratory work and upon successfully passing such an examination shall be granted by the Board of Pharmacy a certificate of registration as a registered pharmacist in this State upon the surrender of his or her assistant pharmacist certificate. The board may make such rules and regulations as may be necessary therefor.

L.1948, c. 50, p. 136, § 1, eff. April 29, 1948.

45:14-8. Reciprocal registration; fee

The board may waive the examination of any applicant for registration who is registered in the District of Columbia or any State or territory or insular possession of the United States, or any foreign country that has an equivalent standard for registration, and if the board of pharmacy of the District of Columbia, or such other State or territory or insular possession of the United States, or such foreign country, shall grant to pharmacists or assistant pharmacists

registered in accordance with this chapter the same privilege to practice pharmacy in the District of Columbia, or in such other State or territory or insular possession of the United States, or in such foreign country. Such reciprocal registration of certificates shall be subject to such rules and regulations as may, from time to time, be made by the board of pharmacy of this State, and each applicant for such reciprocal registration shall pay the required fee for registration.

Amended by L.1970, c. 331, § 2, eff. Dec. 29, 1970.

45:14-8.1. Pharmacist registered in another state; examination not necessary

The board of pharmacy may grant reciprocal registration without examination to any applicant for registration as a pharmacist who is duly registered as such in any of our sister States having a standard for registration equivalent to that of this State and who has practiced pharmacy as a registered pharmacist in such State for a period of 25 years or more immediately preceding his application for registration in this State, notwithstanding that the school or college of pharmacy from which such applicant graduated was not at the time of his graduation a school or college of pharmacy approved by the board; provided, that such school or college presently is approved by the board; and provided, further, that such applicant is otherwise qualified for reciprocal registration pursuant to section 45:14-8 of the Revised Statutes.

L.1969, c. 164, § 1, eff. Sept. 17, 1969.

45:14-9. Assistant pharmacists; registration discontinued; privileges of existing assistant pharmacists

From and after July first, one thousand nine hundred and thirty-two, the board shall discontinue the registration of assistant pharmacists.

All duly registered assistant pharmacists in good standing on the record books of the board on April eighteenth, one thousand nine hundred and thirty-two, shall be entitled to all the privileges of a registered pharmacist during the temporary absence of the registered pharmacist in charge, but shall not be entitled to engage in business on their own account, or as a manager to conduct a pharmacy or drug store. The term “temporary absence” as used in this section shall mean an absence of not more than four hours in any one day of twenty-four hours.

45:14-9.1. Licenses to aliens; ultimate citizenship essential to continuance of license

Applicants examined and licensed in accordance with the provisions of this chapter who, when admitted to the licensing examination, were citizens of a foreign country, and who had declared intention of becoming citizens of the United States, shall, upon passing the examination, be issued a license valid for six years from the date of such declaration of intention and upon failure of such licensee to furnish evidence of his having actually become a citizen, his license shall become invalid and automatically become revoked and his registration shall be annulled.

45:14-10. Display of certificates; sign to bear name of registered pharmacist in charge

Every registered pharmacist owning, conducting or employed in any drug store or pharmacy, and every registered assistant pharmacist employed in any drug store or pharmacy, shall conspicuously display his certificate of registration and renewal certificate in said pharmacy or drug store, and any failure so to do shall be prima facie

evidence that such person is not a registered pharmacist. Every pharmacy in this state must have displayed on a sign, so as to be read from the outside, the name of the registered pharmacist who is in charge.

45:14-11. Annual renewal of certificate; fees

Every registered pharmacist and every registered assistant pharmacist shall, annually, on such date as the board shall prescribe, pay to the secretary of the board the required registration renewal fee in return for which he shall receive a renewal certificate of registration.

Amended by L.1952, c. 138, p. 489, § 1, eff. July 1, 1952; L.1970, c. 331, § 3, eff. Dec. 29, 1970.

45:14-11.1. Renewal of certificates of persons honorably discharged from military or naval service; fee; "in time of emergency'' defined

Any person, who after September sixteenth, one thousand nine hundred and forty, has entered or hereafter shall enter the active military or naval service of the United States during the present war or heretofore or hereafter in time of emergency entered or shall enter the armed forces of the United States who, at the time of such entry, held or shall hold, in full force and effect, a certificate of registration as a registered pharmacist or as a registered assistant pharmacist of the State of New Jersey, shall be granted a renewal certificate of registration without the payment of any fee upon presenting to the board of pharmacy of the State of New Jersey an honorable discharge from such military or naval service, or in lieu thereof a certificate of honorable service, dated not more than one year prior to the date of such presentation, notwithstanding that the annual renewal fee or fees have not been paid during the period of such person's military or naval service. Such renewal certificate of registration shall expire on the thirty-first day of December of the year in which issued.

The provisions of this act shall not apply to any person who at the time of his entry into such military or naval service did not hold a current renewal certificate of registration, if such renewal was required by virtue of the provisions of section 45:14-11 of the Revised Statutes.

The board may make such rules and regulations as may be necessary therefor.

As used in this act the term "in time of emergency'' shall mean and include any time after June twenty-third, one thousand nine hundred and fifty, and prior to the termination, suspension or revocation of the proclamation of the existence of a national emergency issued by the President of the United States on December sixteenth, one thousand nine hundred and fifty, or termination of the existence of such national emergency by appropriate action of the President or Congress of the United States.

L.1944, c. 132, p. 363, § 1, eff. April 14, 1944. Amended by L.1945, c. 177, p. 606, § 1, eff. April 17, 1945; L.1952, c. 75, p. 404, § 1, eff. April 23, 1952.

45:14-11.2 to 45:14-11.10. Repealed by L.1995, c. 79, § 7, eff. July 10, 1995

45:14-11.11. Continuing education requirements for pharmacists; supervision by board

The Board of Pharmacy of the State of New Jersey shall require each person registered as a pharmacist, as a condition for biennial certification pursuant to R.S.45:14-11 and P.L.1972, c. 108 (C. 45:1-7), to complete 30

credits of continuing pharmaceutical education and submit proof thereof, as provided in section 2 of this act,[1] during each biennial registration period.

L.1995, c. 79, § 1, eff. July 10, 1995.

[1] N.J.S.A. § 45:14-11.12.

45:14-11.12. Duties of board relating to continuing education requirements

a. The board shall:

(1) Establish standards for continuing pharmaceutical education, including the subject matter and content of courses of study, the selection of instructors, and the type of continuing education credits required of a registered pharmacist as a condition for biennial certification;

(2) Approve educational programs offering credit towards the continuing pharmaceutical education requirements; and

(3) Approve other equivalent educational programs, including, but not limited to, home study courses, and shall establish procedures for the issuance of credit upon satisfactory proof of the completion of these programs.

b. In the case of education courses and programs, each hour of instruction shall be equivalent to one credit.

L.1995, c. 79, § 2, eff. July 10, 1995.

45:14-11.13. Approval of continuing education programs by board

a. In no event shall the board approve a continuing pharmaceutical education program, pursuant to subsection a. of section 2 of this act,[1] that discriminates against any registered pharmacist in this State. The board shall only approve programs that are: provided on a reasonable nondiscriminatory basis; available to all registered pharmacists in this State; and offered in a manner that enables pharmacists from all areas of the State to attend. The board shall permit any pharmaceutical association or organization offering a continuing pharmaceutical education program approved by the board pursuant to section 2 of this act to impose a reasonable differential in registration fees for courses upon registered pharmacists who are not members of that pharmaceutical association or organization. The board may approve programs to be held within or outside of this State.

b. In no event shall the board grant credits for or approve as a component of a continuing pharmaceutical education program, pursuant to subsection a. of section 2 of this act: (1) participation in the routine business portion of any meeting of a pharmaceutical organization; or (2) any presentation that is offered to sell a product or promote a business enterprise.

L.1995, c. 79, § 3, eff. July 10, 1995.

[1] N.J.S.A. § 45:14-11.12.

45:14-11.14. Waiver of continuing education requirements

The board may, in its discretion, waive requirements for continuing pharmaceutical education on an individual basis for reasons of hardship such as illness or disability, retirement of the registration certificate, or other good cause.

L.1995, c. 79, § 4, eff. July 10, 1995.

45:14-11.15. Completion of continuing education credits not required for initial renewal of registration

The board shall not require completion of continuing pharmaceutical education credits for an initial renewal of registration.

L.1995, c. 79, § 5, eff. July 10, 1995.

45:14-11.16. Excess credit hours to be carried over to satisfy continuing education requirements for next biennial certification period

In the event a pharmacist completes a number of continuing education credit hours in excess of the number required by section 1 of this act, the board may allow that these credits be carried over to satisfy the pharmacist's continuing education requirement for the next biennial certification period, but shall not be applicable thereafter.

L.1995, c. 79, § 6, eff. July 10, 1995.

45:14-12. Refusal of examination; suspension or revocation of certificate; person deemed unregistered during suspension or revocation; hearing; court review

In addition to the provisions of section 8 of P.L.1978, c. 73 (C.45:1-21), the board may refuse an application for examination or may suspend or revoke the certificate of a registered pharmacist or a registered assistant pharmacist upon proof satisfactory to the board that such registered pharmacist or such registered assistant pharmacist is guilty of grossly unprofessional conduct and the following acts are hereby declared to constitute grossly unprofessional conduct for the purpose of this act:

a. Paying rebates or entering into an agreement for payment of rebates to any physician, dentist or other person for the recommending of the services of any person.

b. The providing or causing to be provided to a physician, dentist, veterinarian or other persons authorized to prescribe, prescription blanks or forms bearing the pharmacist's or pharmacy's name, address or other means of identification.

c. (Deleted by amendment.)

d. The claiming of professional superiority in the compounding or filling of prescriptions or in any manner implying professional superiority which may reduce public confidence in the ability, character or integrity of other pharmacists.

e. Fostering the interest of one group of patients at the expense of another which compromises the quality or extent of professional services or facilities made available.

f. The distribution of premiums or rebates of any kind whatever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the purposes of this chapter and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is 62 years of age or older. Before a certificate shall be refused, suspended or revoked, the accused person shall be furnished with a copy of the complaint and given a hearing before the board. Any person whose certificate is so suspended or revoked shall be deemed an unregistered person during the period of such suspension or revocation, and as such shall be subject to the penalties prescribed in this chapter, but such person may, at the discretion of the board, have his certificate reinstated at any time without an examination, upon application to the board. Any person to whom a certificate shall be denied by the board or whose certificate shall be suspended or revoked by the board shall have the right to review such action by appeal to the Appellate Division of the Superior Court in lieu of prerogative writ.

g. Advertising of prescription drug prices in a manner inconsistent with rules and regulations promulgated by the Director of the Division of Consumer Affairs; provided, however, no such advertising of any drug or substance shall be authorized unless the Commissioner of Health and Senior Services shall have determined that such advertising is not harmful to public health, safety and welfare.

Amended by L.1952, c. 351, p. 1132, § 1, eff. June 18, 1952; L.1953, c. 43, p. 814, § 69, eff. March 19, 1953; L.1965, c. 120, § 1, eff. June 23, 1965; L.1973, c. 125, § 1, eff. May 10, 1973; L.1977, c. 240, § 2, eff. Sept. 29, 1977.

Amended by L.1999, c. 403, § 11, eff. Jan. 18, 2000.

45:14-12.1. Partial invalidity

If any clause, sentence, paragraph, section or part of this act or the application thereof to any person or circumstances shall, for any reason, be adjudged by a court of competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate the remainder of this act, and the application thereof to other persons or circumstances, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which such judgment shall have been rendered and to the person or circumstances involved. It is hereby declared to be the legislative intent that this act would have been adopted had such
invalid provisions not been included.

L.1965, c. 120, § 3, eff. June 23, 1965.

45:14-12.2. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:14-13. Prescriptions filled only by pharmacist or apprentices duly supervised

No person who is not a registered pharmacist of this State, or an apprentice employed in a pharmacy under the immediate personal supervision of a registered pharmacist, shall compound, dispense, fill or sell prescriptions of physicians, dentists, optometrists, veterinarians, any other medical practitioners, certified nurse midwives, nurse practitioners clinical nurse specialists or physician assistants, licensed or approved to write prescriptions for drugs and medicines.

Amended by L.1991, c. 97, § 7, eff. April 9, 1991; L.1991, c. 377, § 4, eff. Jan. 15, 1993; L.1991, c. 378, § 21, eff. July 13, 1992; L.1991, c. 385, § 3, eff. July 14, 1992.

45:14-14. "Prescription'' defined

The term "prescription'' as used in R.S.45:14-13, and R.S.45:14-15 to R.S.45:14-17 means an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, optometrist, veterinarian, other medical practitioner, a certified nurse midwife, a nurse practitioner/clinical nurse specialist or a physician assistant, licensed or approved to write prescriptions intended for the treatment or prevention of disease in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof, on a New Jersey Prescription Blank obtained from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to section 6 of P.L.1996, c. 154 (C.45:14-14.6), transmitted to pharmacists through word of mouth, telephone, telegraph or other means of communication by a duly licensed physician, dentist, optometrist, veterinarian, other medical practitioner, a certified nurse midwife, a nurse practitioner/clinical nurse specialist or a physician assistant, licensed or approved to write prescriptions intended for the treatment or prevention of disease in man or animals, and such prescriptions received by word of mouth, telephone, telegraph or other means of communication shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be filed by the pharmacist as provided for in R.S.45:14-15, but no prescription, for any narcotic drug, except as provided in section 15 of P.L.1970, c. 226 (C.24:21-15), shall be given or transmitted to pharmacists, in any other manner, than in writing signed by the physician, dentist, veterinarian, other medical practitioner, certified nurse midwife, nurse practitioner/clinical nurse specialist or a physician assistant, giving or transmitting the same, nor shall such prescription be renewed or refilled. The requirement in this section that a prescription for any narcotic drug be given or transmitted to pharmacists in writing signed by the prescriber, shall not apply to a prescription for a Schedule II drug written for a long-term care facility resident or hospice patient if that prescription is transmitted or prepared in compliance with federal Drug Enforcement Administration regulations 21 C.F.R.1306.11(d), (e), (f) and (g).

Amended by L.1952, c. 351, § 2, eff. June 18, 1952; L.1991, c. 97, § 8, eff. April 9, 1991; L.1991, c. 377, § 5, eff. Jan. 15, 1993; L.1991, c. 378, § 22, eff. July 13, 1992; L.1991, c. 385, § 4, eff. July 14, 1992.

Amended by L.1996, c. 154, § 8, eff. Jan. 6, 1997; L.1998, c. 78, § 1, eff. Aug. 14, 1998.

45:14-14.1. Legislative findings and declaration

The Legislature finds and declares that the welfare of the citizens of this State and the financial integrity of the governmental reimbursement programs administered for their benefit are threatened by the growing problem of prescription drug abuse, particularly the widespread trafficking in forged and altered prescriptions for oral drugs and items; the submission of these forged prescriptions for payment by State and federal funds through the Medicaid, Pharmaceutical Assistance to the Aged and Disabled, and general assistance programs and by private health insurers drive the cost of health care up for all citizens of New Jersey; and to reduce the ease with which such forgeries can be accomplished and to deter drug abuse, the implementation of a program by which prescriptions shall be written on a uniform prescription blank, printed on non-reproducible, non-erasable safety paper, subject to stringent security controls, is required.

The Legislature further finds and declares that it is likely that prior authorization programs to control fraud and abuse may become unnecessary upon the passage and implementation of P.L.1996, c. 154 (C. 45:14-14.1 et al.).

L.1996, c. 154, § 1, eff. Jan. 6, 1997.

45:14-14.2. Licensed prescribers to use New Jersey prescription blanks

a. Beginning 180 days after the effective date of P.L.1996, c. 154 (C. 45:14-14.1 et al.), a licensed prescriber shall use non-reproducible, non-erasable safety paper New Jersey Prescription Blanks bearing that prescriber's license number whenever the prescriber issues prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items. The prescription blanks shall be secured from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety.

Notwithstanding the provisions of this subsection to the contrary, the Director of the Division of Consumer Affairs may temporarily suspend the operative date of this subsection if the director finds that an insufficient number of licensed prescribers have obtained the required prescription blanks by the operative date with the result that persons seeking to have prescriptions filled would be substantially inconvenienced. The director shall promptly notify the licensed prescribers of the new operative date of this subsection.

b. A licensed prescriber shall maintain a record of the receipt of New Jersey Prescription Blanks. The prescriber shall notify the Office of Drug Control in the Division of Consumer Affairs as soon as possible but no later than 72 hours of being made aware that any New Jersey Prescription Blank in the prescriber's possession has been stolen. Upon receipt of notification, the Office of Drug Control shall take appropriate action, including notification to the Department of Human Services and the Attorney General.

L.1996, c. 154, § 2, eff. Jan. 6, 1997.

45:14-14.3. Health care facilities to use New Jersey prescription blanks

a. Beginning 180 days after the effective date of P.L.1996, c. 154 (C. 45:14-14.1 et al.), prescriptions issued by a health care facility licensed pursuant to P.L.1971, c. 136 (C. 26:2H-1 et seq.) shall be written on non-reproducible, non-erasable safety paper New Jersey Prescription Blanks. The prescription blanks shall be secured from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety. The New Jersey Prescription Blanks shall bear the unique provider number assigned to that health care facility for the issuing of prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items.

Notwithstanding the provisions of this subsection to the contrary, the Director of the Division of Consumer Affairs may temporarily suspend the operative date of this subsection if the director finds that an insufficient number of licensed health care facilities have obtained the required prescription blanks by the operative date with the result that persons seeking to have prescriptions filled would be substantially inconvenienced. The director shall promptly notify the licensed health care facilities of the new operative date of this subsection.

b. A health care facility shall maintain a record of the receipt of New Jersey Prescription Blanks. The health care facility shall notify the Office of Drug Control in the Division of Consumer Affairs as soon as possible but no later than 72 hours of being made aware that any New Jersey Prescription Blank in the facility's possession has been stolen. Upon receipt of notification, the Office of Drug Control shall take appropriate action, including notification to the Department of Human Services and the Attorney General.

L.1996, c. 154, § 3, eff. Jan. 6, 1997.

45:14-14.4. Pharmacists prohibited from filling prescription not issued on New Jersey prescription blank

a. Beginning 180 days after the effective date of P.L.1996, c. 154 (C. 45:14-14.1 et al.), a prescription issued by a licensed prescriber or health care facility shall not be filled by a pharmacist unless the prescription is issued on a New Jersey Prescription Blank bearing the prescriber's license number or the unique provider number assigned to a health care facility, as required pursuant to section 2 or 3 of P.L.1996, c. 154 (C. 45:14-14.2 or 45:14-14.3).

Notwithstanding the provisions of this subsection to the contrary, the Director of the Division of Consumer Affairs in the Department of Law and Public Safety may temporarily suspend the operative date of this subsection if the director finds that an insufficient number of licensed prescribers or licensed health care facilities have obtained the required prescription blanks by the operative date with the result that persons seeking to have prescriptions filled would be substantially inconvenienced. The director shall notify licensed pharmacists of the new operative date of this subsection.

b. Notwithstanding the provisions of subsection a. of this section to the contrary, for the 90 days following the 180-day period or such other operative date as may be determined by the Director of the Division of Consumer Affairs pursuant to subsection a. of this section, a pharmacist, prior to filling a prescription, shall request verification, in writing or orally, of the prescription from the prescriber or health care facility if the pharmacist receives a prescription that is not issued on a New Jersey Prescription Blank as required by section 2 or 3 of P.L.1996, c. 154 (C. 45:14-14.2 or 45:14-14.3).

L.1996, c. 154, § 4, eff. Jan. 6, 1997.

45:14-14.5. Transmission of prescription to pharmacist by telephone or electronic means; prescriber's registration or license number required

Nothing contained in P.L.1996, c. 154 (C. 45:14-14.1 et al.) shall preclude a licensed prescriber from transmitting to a pharmacist by telephone or electronic means a prescription, as otherwise authorized by law, if that prescriber provides the prescriber's Drug Enforcement Administration registration number or prescriber's license number, as appropriate, to the pharmacist at the time the prescriber transmits the prescription.

L.1996, c. 154, § 5, eff. Jan. 6, 1997.

45:14-14.6. Establishment of format for uniform prescription blanks

a. The Division of Consumer Affairs in the Department of Law and Public Safety shall establish the format for uniform, non-reproducible, non-erasable safety paper prescription blanks, to be known as New Jersey Prescription Blanks, which format shall include an identifiable logo or symbol that will appear on all prescription blanks. The division shall establish the format and solicit vendors within 10 days after the effective date of P.L.1996, c. 154. The division shall, within 45 days of the effective date of P.L.1996, c. 154, approve a sufficient number of vendors to ensure production of an adequate supply of New Jersey Prescription Blanks for licensed prescribers and health care facilities Statewide.

b. The Division of Consumer Affairs shall mail to all licensed prescribers in this State designated under R.S. 45:14-14 to write prescriptions, to all licensed pharmacists and to all licensed health care facilities a notice of the requirements of P.L.1996, c. 154 (C. 45:14-14.1 et al.) and the names and addresses of the vendors approved to

produce New Jersey Prescription Blanks. The notice shall be mailed 30 days prior to the operative date of sections 2, 3 and 4 of P.L.1996, c. 154 (C. 45:14-14.2, C. 45:14-14.3 and C. 45:14-14.4).

L.1996, c. 154, § 6, eff. Jan. 6, 1997.

45:14-15. Prescriptions to be numbered and filed; removal of original prescriptions by board or agents

The registered pharmacist compounding, dispensing, filling or selling a prescription shall place the original written prescription in a file kept for that purpose for a period of not less than five years if such period is not less than two years after the last refilling, and affix to the container in which the prescription is dispensed, a label bearing the name and complete address of the pharmacy or drug store in which dispensed, the brand name or generic name of the product dispensed unless the prescriber states otherwise on the original written prescription, the date on which the prescription was compounded and an identifying number under which the prescription is recorded in his files, together with the name of the physician, dentist, optometrist, veterinarian, other medical practitioner, certified nurse midwife, nurse practitioner clinical nurse specialist or physician assistant, prescribing it and the directions for the use of the prescription by the patient, as directed on the prescription of the physician, dentist, optometrist, veterinarian, other medical practitioner, certified nurse midwife, nurse practitioner clinical nurse specialist or physician assistant, licensed or approved to write prescriptions. Every registered pharmacist who fills or compounds a prescription, or who supervises the filling or compounding of a prescription by a person other than a pharmacist registered in this State, shall place his name or initials on the original prescription or on the label affixed to the container in which the prescription is dispensed or in a book kept for the purpose of recording prescriptions. The Board of Pharmacy or any of its agents is hereby empowered to inspect the prescription files and other prescription records of a pharmacy and to remove from said files and take possession of any original prescription, providing, that the authorized agent removing or taking possession of an original prescription shall place in the file from which it was removed a copy certified by said person to be a true copy of the original prescription thus removed; provided further, that the original copy shall be returned by the Board of Pharmacy to the file from which it was removed after it has served the purpose for which it was removed.

Amended by L.1952, c. 137, p. 487, § 1, eff. July 1, 1952; L.1979, c. 146, § 1, eff. Oct. 14, 1979; L.1991, c. 97, § 9, eff. April 9, 1991; L.1991, c. 377, § 6, eff. Jan. 15, 1993; L.1991, c. 378, § 23, eff. July 13, 1992; L.1991, c. 385, § 5, eff. July 14, 1992.

45:14-15.1. Pharmacists to conduct prospective drug review for new prescriptions; review optional before refilling a prescription

a. A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. The review shall include screening for potential drug therapy problems due to:

(1) therapeutic duplication;

(2) drug-disease contraindications to the extent the diagnosis information is available;

(3) drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs;

(4) incorrect drug dosage or duration of drug treatment;

(5) drug-allergy interactions; and

(6) clinical abuse or misuse.

b. A pharmacist may conduct a prospective drug review in accordance with the provisions of this section before refilling a prescription to the extent he deems appropriate in his professional judgment.

L.1993, c. 120, § 1, eff. Aug. 25, 1993.

45:14-15.2. Pharmacists to offer to counsel persons presenting a new prescription for filling; forms of counselling

a. A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment, and shall include any one or a combination of the following:

(1) Face-to-face communication with the pharmacist;

(2) Face-to-face communication with ancillary personnel; or

(3) By telephone.

For the purpose of Medicaid or other third-party reimbursement or payment programs, any of the above methods, or a combination of them, shall constitute an acceptable offer to provide counseling except to the extent this subsection is inconsistent with regulations promulgated by the federal Health Care Financing Administration pursuant to 42 U.S.C. § 1396r-8(g)(2)(A)(ii).[1]

b. If, in the professional judgment of the pharmacist, it is inappropriate to verbally make the offer to counsel, the offer to counsel may be made in a written communication.

c. A pharmacist may offer to counsel any person who receives a refill prescription in accordance with the provisions of this section to the extent he deems appropriate in his professional judgment.

d. If the offer to counsel is accepted, the pharmacist shall counsel the person presenting the prescription to the extent the pharmacist deems appropriate in his professional judgment. Counseling shall be performed by the pharmacist himself and may, but need not, include the following:

(1) The name and description of the medication;

(2) The dosage form, dosage, route of administration, and duration of drug therapy;

(3) Special directions and precautions for preparation, administration, and use by the patient;

(4) Common adverse or severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(5) Techniques for self-monitoring drug therapy;

(6) Proper storage;

(7) Prescription refill information; and

(8) Action to be taken in the event of a missed dose.

e. Nothing in this section shall be construed as requiring a pharmacist to provide counseling when the person presenting the prescription fails to accept the pharmacist's offer to counsel. If the prescription is filled for a person residing outside of the local telephone calling area of the pharmacy, the pharmacist shall either provide a toll-free telephone number or accept reasonable collect calls from the person.

L.1993, c. 120, § 2, eff. Aug. 25, 1993.

[1] 42 USCA § 1396r-8(g)(2)(A)(ii).

45:14-15.3. Patient profile system to be maintained for all persons for whom prescriptions are dispensed; contents of profile

a. A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The patient profile record system shall be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record may be maintained for members of a family living at the same address and
possessing the same family name.

b. The following information generated at the individual pharmacy shall be recorded in the patient profile system:

(1) The family name and the first name of the person for whom the medication is intended (the patient);

(2) The address and telephone number of the patient;

(3) Indication of the patient's age, birth date or age group (infant, child, adult) and gender;

(4) The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other record approved by the New Jersey State Board of Pharmacy;

(5) The number or designation identifying the prescription;

(6) The prescriber's name;

(7) The name, strength and quantity of the drug dispensed;

(8) Individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devises; and

(9) Any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

c. The information obtained shall be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records, and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

L.1993, c. 120, § 3, eff. Aug. 25, 1993.

45:14-15.4. Exceptions

The provisions of this act shall not apply to any drug dispensed to an inpatient of a hospital or nursing home, except to the extent required by regulations promulgated by the federal Health Care Financing Administration implementing 42 U.S.C. § 1396r-8(g)(2)(A).[1]

L.1993, c. 120, § 4, eff. Aug. 25, 1993.

[1] 42 USCA § 1396r-8(g)(2)(A).

45:14-16. Prescription must be strictly followed

It shall be deemed a violation of sections 45:14-13 to 45:14-15 of this Title if a prescription as compounded, filled, dispensed or sold is found to contain more or less than the quantity of the ingredient or several or combined ingredients specified by the prescriber, or if the prescription as compounded, filled, dispensed or sold is found to contain an ingredient or ingredients or a brand of ingredient or ingredients other than those specified by the prescriber, except that the addition of such inert ingredients as are required in the art of compounding shall be permissible, but such ingredients shall in no manner be used to replace the ingredient or several or combined ingredients specified by the prescriber, without the prescriber's permission having been obtained.

Amended by L.1953, c. 329, p. 1877, § 1, eff. July 29, 1953.

45:14-16.1. Liability for violations

For violations of sections 45:14-13, 45:14-14, 45:14-15 and 45:14-16 of the Revised Statutes, the registered pharmacist or other person who either compounds, fills, dispenses or sells a prescription or who supervises the compounding, filling, dispensing or sale of a prescription by a person other than a pharmacist registered in this State, and the owner of a pharmacy in which a violation occurs, shall be held equally liable, except that no liability shall be attached to the owner of a pharmacy if in the opinion of the board such liability does not exist, and the payment of a penalty for any such violation shall constitute an offense.

L.1953, c. 329, p. 1877, § 2, eff. July 29, 1953.

45:14-17. Enforcement

The board shall have power to make rules and regulations for the enforcement of sections 45:14-13 to 45:14-16 of this title, including the establishing of tolerances to allow for deviations from the amounts of ingredients prescribed due to manipulative procedures and deterioration.

45:14-18. Sale or delivery of poisons to children, etc., and certain methods of procuring poisons, prohibited

No person shall sell or deliver to any minor under twelve years of age or of any person known to be of unsound mind or under the influence of liquor, any of the substances enumerated in schedule "A'' or schedule "B'' appended to sections 45:14-19 and 45:14-20 of this title, respectively, or any other poisonous drug, chemical, or medicinal substance. No person shall give a fictitious name or make any false representation to the seller in order to procure any poison.

45:14-19. Dispensing of certain poisons regulated; schedule "A''

No person shall sell at retail, give away, or dispense any of the poisons enumerated in schedule "A'', appended to this section or any other substance commonly recognized as a deadly poison, or any substance which, according to standard works on medicine, materia medica or toxicology, is liable to be destructive of adult human life in doses of five grains or less, without distinctively labeling the package, bottle, box, can, container or wrapper in which said poison is contained with a red label stating the name of the article in English, the word "poison'' and the name and place of business of the dispenser. Before delivery shall be made, the seller must first learn by inquiry that the person to whom delivery is made is aware of the dangerous character of the poison and is a proper person to purchase such poison, and that it is desired for a legitimate purpose. Before making such delivery, the seller shall also record in a book kept solely for that purpose the date and hour, the name of the article, the quantity delivered, the use stated by the purchaser, and the name and address of the purchaser, which poison record shall be preserved for at least five years after the date of the last entry, and shall at all times be open to the inspection of any member or agent of the board, or to any proper officer of the law.

Schedule "A''

Arsenic and the compounds and chemical derivatives of arsenic, corrosive sublimate and other poisonous compounds and derivatives of mercury, phosphorous[1] and its poisonous compounds and derivatives, tartar emetic or other poisonous salts or compounds of antimony, hydrocyanic acid, prussic acid, potassium cyanide, other cyanides and prussiates or other poisonous compounds and derivatives of cyanogen, oil of bitter almonds containing hydrocyanic acid, opium and its preparations and derivatives, aconite and its preparations, belladonna and its preparations, calabar bean and its preparations, scopola and its preparations, strophanthus and its preparations, the following organic principles: Aconitine, apomorphine, atropine, brucine, cantharidin, cocaine, codeine, coniine, digitalin, emetine, eucaine, gelsemine, homatropine, hyoscine, hyoscyamine, morphine, diacetylmorphine or heroin, ethyl morphine or dionin, physostigmine or eserine, scopolamine, strophanthin, strychnine, veratrine or any of their chemical compounds, salts or derivatives, or any other drug, chemical substance, or preparation which, according to standard works on medicine, materia medica, or toxicology, is liable to be destructive to adult human life in doses of five grains or less.

[1]So in Revised Statutes.

45:14-20. Dispensing of certain poisons regulated; schedule "B''

No person shall sell at retail or dispense any of the poisons enumerated in schedule "B'', appended to this section or any other substance recognized by standard authorities on medicine, materia medica or toxicology as poisonous without first learning by inquiry that the person to whom delivery is made is aware of the poisonous character of the substance, and is a proper person to purchase such drugs, and that it is desired for a legitimate purpose, and, before making such delivery, the package, bottle, box, can, container or wrapper in which said poison is contained must be labeled with a red label stating the name of the article in English, the word "poison'' and the name and place of business of the dispenser.

Schedule "B''

Cannabis, cantharides, Chinese blistering beetle, cocculus indicus, colchicum, cotton root bark, digitalis, ergot, gelsemium, hellebore, henbane, ignatia amara, phytolacca, nux vomica, veratrum, stramonium, savin, chloroform, ether, wood or methyl alcohol, white precipitate, red precipitate, silver nitrate, copper salts, salts of barium, lead salts, oxalic acid, mineral acids, arsenical solutions, iodine, tincture of iodine, carbolic acid, creosote, croton oil, oils of pennyroyal, rue, savin or tansy or any other drug, chemical, substance, or preparation which according to standard works on medicine, materia medica, or toxicology, while not considered as toxic in doses of five grains or less is, nevertheless, liable to be destructive of adult human life in doses of sixty grains or less.

45:14-21. Application of sections 45:14-19 and 45:14-20 limited

The provisions of sections 45:14-19 and 45:14-20 of this title shall not apply (a) to poisons sold or dispensed upon prescription directed by a registered practitioner of medicine, dentistry or veterinary medicine, and all such prescriptions shall be filed by the dispenser and kept for a period of at least five years; (b) to sales of poisons made to registered practitioners of medicine, dentistry, pharmacy or veterinary medicine; (c) to sales made by any manufacturer, wholesaler or licensed pharmacist, to another manufacturer, wholesaler or licensed pharmacist, or to a manufacturer of proprietary medicine, or to a hospital, college, school, or scientific or public institution, or to the sale of such poisons as are used in the arts, agriculture, or in manufacturing, to persons known to be engaged in such pursuits and believed to be making the purchase for legitimate use, if such poisons are properly labeled with a red label, stating the name of the article in English, the word "poison'' and the name and address of the seller; or (d) to the sale, distribution, giving away, dispensing or possession of preparations or remedies which do not contain more than two grains of opium, or more than one-fourth of a grain of morphine, or more than one-eighth of a grain of heroin, or more than one grain of codeine, or any salt or derivative of any of them in one fluid ounce, or, if a solid or semi-solid preparation, in one avoirdupois ounce; or to plasters, liniments, ointments or other preparations which are prepared for external use only, if such remedies and preparations are sold, distributed, given away or dispensed or possessed as medicines and not for the purpose of evading the intentions and provisions of said sections.

45:14-22. Board to furnish printed schedules of poisons and antidotes

Printed schedules of all such named poisons, and the antidotes approved by the board, shall be given to all registered pharmacists and other persons applying therefor; and the board, upon request, shall furnish any dealer with a list of articles, preparations and compounds, the sale of which is prohibited or regulated by sections 45:14-19 and 45:14-20 of this title. The board shall adopt and have printed a schedule of what in its judgment are the most suitable antidotes for the various poisons, and shall forward by mail one copy to each person registered upon its books, and to every other person applying for the same. The particular antidotes may be printed upon the labels of pharmacists

as being those officially approved by the board. The board may revise and amend the schedule of antidotes recommended, from time to time, as it may deem advisable.

45:14-23. Hypnotic and somnifacient drugs sold on prescription only, records; exceptions

No barbital or any other hypnotic or somnifacient drug, as defined herein, shall be sold at retail or dispensed to any person except upon the written prescription of a duly licensed physician, dentist, or veterinarian, compounded or dispensed by a registered pharmacist or under the immediate personal supervision of a registered pharmacist and no pharmacist shall dispense any such drug without affixing to the container in which the drug is sold or dispensed a label bearing the name and address of the pharmacist, the date compounded and the consecutive number of the prescription under which it is recorded in his prescription files, together with the name of the physician, dentist or veterinarian prescribing it, and the directions for the use of the drug by the patient as given upon the prescription of the physician, dentist or veterinarian, but the provisions of this section shall not apply to a duly licensed physician, dentist, or veterinarian, when in their judgment they deem it advisable to dispense any of the aforementioned drugs to their patients under their immediate supervision, but they shall keep a record of the date, the drug dispensed, the quantity, and the name and address of the patient. No such prescription shall be renewed or refilled, except by authorization of the physician, dentist, veterinarian or other medical practitioner who signed the same.

Amended by L.1952, c. 351, p. 1134, § 3, eff. June 18, 1952.

45:14-24. Labels

No manufacturer, pharmacist, jobber or other dealer in drugs shall sell or have in his possession barbital or any other hypnotic or somnifacient drug, unless the container bears a label securely attached thereto stating conspicuously in printed words the specific name of the barbital or other hypnotic or somnifacient drug and the proportion or amount thereof. Such label shall not be necessary when such a drug is dispensed by a pharmacist upon a prescription and the container is labeled in the manner described in section 45:14-23 of this title.

45:14-25. “Barbital’’ and “other hypnotic and somnifacient drugs’’ defined

For the purpose of sections 45:14-23 and 45:14-24 of this title the term “barbital’’ shall mean and include, the salts of barbituric acid, also known as malonyl urea, or any derivative or compounds of any preparations or mixtures thereof possessing hypnotic properties or effects, and the term “other hypnotic or somnifacient drug’’ shall mean and include sulphonethylmethane (trional) or sulphonmethane (sulphonal) or diethylsulphon diethylmethane (tetronal) or carbromal, by whatever name they may be known, or paraldehyde or any derivatives or compounds or preparations or mixtures thereof possessing hypnotic properties or effects, and chloral or chloral hydrate or chlorbutanol or any compounds or mixtures thereof possessing hypnotic properties or effects, when such barbital or other hypnotic and somnifacient drugs, or any derivatives or compounds or mixtures or preparations thereof are to be used internally. This section shall not apply to any compound or mixture or preparation that is intended to be used as a spray or a gargle or a liniment or in any other wise for external application only, provided such compound or mixture or preparation intended for external application only shall contain, in addition to the content of barbital or other hypnotic or somnifacient drug, some other drug or drugs conferring upon it medicinal qualities other than those possessed by the barbital or other hypnotic or somnifacient drugs alone, and such compounds or mixtures or preparations shall be sold in good faith for the purpose for which they are intended, and not for the purpose of evading the provisions of sections 45:14-23 to 45:14-26 of this title.

45:14-26. Enforcement

The board shall have power to enforce the provisions of sections 45:14-23 to 45:14-25 of this title, and shall make rules and regulations for their enforcement.

45:14-26.1. Drugs dispensed only by prescription; selling or furnishing; refilling prescriptions; exceptions

No person, who is not a registered pharmacist or an apprentice employed in a pharmacy or drug store under the immediate personal supervision of a registered pharmacist, or who is not a duly licensed physician, dentist, veterinarian or other person licensed to prescribe drugs shall sell, dispense, or furnish any drug the label of which by law or regulations of the State Department of Health or Federal Food and Drug Administration is required to bear a statement that it is to be dispensed only by or on the prescription of a physician, dentist, veterinarian or other person licensed to prescribe drugs, or words of similar or like import; nor shall any registered pharmacist, or any apprentice employed in a pharmacy or drug store under the immediate personal supervision of a registered pharmacist, sell, dispense, or furnish any such drug except upon the prescription of a duly licensed physician, dentist, veterinarian or other person licensed to prescribe such drug. Such prescription shall not be refilled except on the authorization of the prescribing physician, dentist, veterinarian or other person licensed to write such prescription.

The provisions of this act shall not apply to the sale of any such drug by a manufacturer or wholesaler or pharmacy to each other or to or by a physician, dentist, veterinarian or other person licensed to prescribe such drug in their professional practice.

L.1949, c. 93, p. 411, § 1, eff. May 11, 1949.

45:14-26.2. Enforcement of act

The Board of Pharmacy in the Division of Professional Boards in the Department of Law and Public Safety shall have the power to enforce the provisions of this act, and shall make such reasonable rules and regulations not inconsistent with the provisions of this act as may be necessary therefor.

L.1949, c. 93, p. 411, § 2, eff. May 11, 1949.

45:14-26.3. Repealed by L.1979, c. 432, § 1, eff. Feb. 14, 1980

45:14-27. Penalties for violations

Whoever, not being a duly registered pharmacist of this state, establishes or conducts any pharmacy or drug store for the retailing, dispensing or compounding of drugs, medicines, physicians' prescriptions or poisons or whoever, not having first obtained a certificate of registration as a pharmacist or registered assistant in accordance with the provisions of this chapter, engages as clerk or assistant or apprentice in any store or pharmacy and retails, dispenses or compounds drugs, medicines or physicians' prescriptions, or whoever, being a duly registered pharmacist or registered assistant or an apprentice, violates any of the provisions of this chapter, or adulterates or sells any adulterated drug, medicine or chemical, or whoever procures or attempts to procure registration for himself or any other person under this chapter by making or causing to be made any false representations, or fraudulently represents himself to be registered in accordance with this chapter, or whoever violates any of the provisions of this chapter shall forfeit and pay a penalty as provided in section 45:14-37 of this title, to be sued for and recovered in the

manner provided in sections 45:14-37 and 45:14-38 of this title. All penalties collected under the provisions of this chapter shall be paid to the treasurer of the board.

45:14-28. Repealed by L.1979, c. 432, § 6, eff. Feb. 14, 1980

45:14-29. Application of provisions of chapter limited

Except as otherwise provided as to barbital or any other hypnotic or somnifacient drugs, nothing in this chapter shall be construed to apply to or in any manner interfere with the strictly professional pursuits of any physician, the making and vending of nonpoisonous patent or proprietary medicines, the sale of simple nonpoisonous domestic remedies by retail dealers in rural districts, nor the ownership of any pharmacy or store, in whole or in part, by a person not a registered pharmacist, if such pharmacy or store is at all times in charge of a registered pharmacist. Any person holding any certificate of registration granted under any former act, with the renewal certificate thereof, shall be considered a registered pharmacist within the meaning of this chapter.

45:14-30. Use of words "pharmacy'' and "drug store'' limited

No person shall carry on, conduct, or transact business under a name which contains as a part thereof the words "pharmacist'', "pharmacy'', "apothecary'', "apothecary shop'', "chemist's shop'', "drug store'', "druggist'', "drugs'', or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign, or otherwise describe or refer to the place of business conducted by him by the terms "pharmacy'', "apothecary'', "apothecary shop'', "chemist's shop'', "drug store'', "drugs'', or any word or words of similar or like import, unless the place of business so conducted is a drug store or pharmacy operated or managed at all times by a registered pharmacist.

45:14-31. Certain establishments unaffected

Nothing in section 45:14-30 of this title shall interfere with the ownership of a pharmacy or store, in whole or in part, by a person not a registered pharmacist, if such pharmacy or store is at all times in charge of a registered pharmacist.

45:14-32. Registration of pharmacy or drug store; permit required; definitions; institutional permit

No pharmacy or drug store shall be opened or kept open for the transaction of business or for rendering professional services until or unless it has been registered with and a permit therefor has been issued to it by the board.

The terms "pharmacy'' and "drug store'' as used in this section and in sections 45:14-33 to 45:14-36 of this title mean an establishment or place of business which, under the provisions of this chapter, is required to be operated or managed at all times by a registered pharmacist.

Nothing contained in this section shall be construed as prohibiting the dispensing of drugs in a hospital, nursing home, convalescent center, industrial dispensary, medical clinic or similar institution; provided, however, that such institution shall have first obtained a permit from the board, which shall be designated as an institutional permit. Where such institution does not have a pharmacy on its premises, it may enter into an agreement for pharmaceutical services with a pharmacy registered in this State. The registered pharmacist shall be responsible for maintaining such records and controls as may be required by the board.

Drugs dispensed under such institutional permits shall be dispensed only to in-patients, employees of the institution and out-patients who are treated by staff members of the institution in their respective clinics.

The board may adopt rules and regulations establishing minimum standards for the amount of equipment, supplies, physical space, hours of operation and other requirements relating to the compounding and dispensing of prescription items by such institutions.

The fees charged by the board for the issuance, transfer or renewal of an institutional permit shall be the same as the fees charged for a regular pharmacy permit.

Amended by L.1971, c. 248, § 1, eff. June 30, 1971.

45:14-33. Permit; application; fee; display; prerequisites

Upon application made on a form prescribed and furnished to the board, and upon payment of the required fee, the board shall issue a permit to conduct a new pharmacy to such persons as it shall deem qualified to conduct such business. The permit so issued shall be exposed in a conspicuous place in the pharmacy for which it was issued and shall not be transferable and shall expire June 30 following the date on which the permit is issued. Whenever the application to conduct a pharmacy pertains to an establishment for which a permit has already been issued by the board and such pharmacy is in active operation under an unsuspended or unrevoked permit, the application shall be made on a form prescribed and furnished by the board and shall be accompanied by the required fee, and the board shall issue a permit transferring authority to conduct such pharmacy to the person making application if he shall be deemed qualified to conduct such business. The permit so issued shall be exposed in a conspicuous place in the pharmacy for which it was issued and shall not be transferable and shall expire on June 30 following the date of issuance of the permit. No permit shall be issued unless it appears to the satisfaction of the board that:

a. The management of the pharmacy is in personal and continuous charge of a pharmacist registered in accordance with the laws of this State.

b. The pharmacy for which the permit is sought will be conducted in full compliance with the law and with rules and regulations of the said board.

c. The location and facilities of said pharmacy are such that it can be operated and maintained without endangering the public health or safety.

d. The said pharmacy shall offer complete pharmaceutical service by compounding or dispensing all prescriptions which may reasonably be expected to be compounded or dispensed by the pharmacist; and

e. The said pharmacy shall not offer professional services under terms and conditions which tend to interfere with or impair the free and complete exercise of professional judgment and skill or enter into any agreement which denies the patient the right of free choice of pharmacies.

Amended by L.1939, c. 85, p. 171, § 2, eff. June 6, 1939; L.1965, c. 120,
§ 2, eff. June 23, 1965; L.1970, c. 331, § 4, eff. Dec. 29, 1970.

45:14-34. Annual registration; form of application; separate permit for each establishment

On or before July 1 of each year the owner or manager of any pharmacy or drug store engaged in business in this State shall renew such registration and obtain a permit from the board and pay the required annual fee. At the time of such annual or original registration such owner or manager shall furnish to the board a complete list of those who are engaged in such business as registered pharmacists, registered assistant pharmacists and apprentices, and this list shall be furnished with each original and annual registration. The application for such a permit or license shall indicate the name of the owner, manager, trustee, leasee, received[1] or other person or persons desiring such permit, as well as the location of such pharmacy or drug store, including street and number and such other information as the board may request. If it is desired to operate, manage, open or establish more than one pharmacy or drug store, separate application shall be made and a separate permit or license shall be issued for each such pharmacy or drug store. If an application is found satisfactory the secretary of the board shall issue to the applicant a permit or license for each pharmacy or drug store for which an application is made. Permits or licenses so issued shall not be transferable and shall expire on June 30 of each year.

Amended by L.1939, c. 85, p. 172, § 3, eff. June 6, 1939; L.1950, c. 132, p. 249, § 1, eff. May 12, 1950; L.1970, c. 331, § 5, eff. Dec. 29, 1970.

[1]So in enrolled bill. Probably should read “lessee, receiver’’.

45:14-35. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:14-36. Enforcement; rules and regulations

The board may enforce the provisions of sections 45:14-32 to 45:14-35 of this title and shall make such rules and regulations as may be necessary therefor.

45:14-36.1. Rules and regulations by Board of Pharmacy

The Board of Pharmacy may promulgate rules and regulations setting up minimum requirements regarding adequate facilities for the safe storage of narcotic drugs; equipment for the prescription departments in pharmacies and drug stores; stock of drugs, pharmaceuticals and chemicals in prescription departments of pharmacies and drug stores; size and other space requirements of prescription departments; and other facilities necessary in the compounding of prescriptions; and may promulgate rules and regulations governing sanitation, orderliness and cleanliness in the pharmacy or drug store.

L.1948, c. 105, p. 559, § 1, eff. May 28, 1948. Amended by L.1952, c. 107, p. 447, § 1, eff. April 28, 1952.

45:14-36.2. Temporary permits; limited permits

The board may issue a temporary permit which may grant to the owner of a pharmacy or drug store the privilege of compounding or dispensing prescriptions pending compliance with all of the requirements of this chapter and the rules and regulations promulgated by the board. The board may also grant at its discretion to the owner of a pharmacy or drug store a limited permit which does not allow the compounding and dispensing of prescriptions and any pharmacy or drug store operating under a limited permit shall be subject to all of the requirements of this chapter and all rules and regulations promulgated by the board with the exception of those pertaining specifically to the prescription department and its contents. No permit of any kind, however, shall be issued by the board unless

an application has been made therefor and a fee paid as prescribed in Revised Statutes, section 45:14-33. A temporary permit or a limited permit in effect on June thirtieth of any year shall expire on that date and registration of the pharmacy or drug store must be renewed on or before July first in the manner prescribed for renewal of registration of pharmacies and drug stores operating under other permits granted by the board.

L.1948, c. 105, p. 560, § 2, eff. May 28, 1948.

45:14-36.3. Extension or renewal of temporary permit; suspension or revocation of permits; review

A temporary permit of any nature issued by the board shall not be extended or renewed beyond the period for which it was issued unless an application for its extension or renewal is filed by the applicant. Such application may be acted upon by the board without payment of a fee unless the temporary permit is in effect on June 30 of any year when it shall expire and must be renewed on or before July 1 in the manner prescribed for renewal of registration of pharmacies and drug stores operating under other permits issued by the board. Any other permit issued by the board may be suspended or revoked by the board (a) for failure to meet any of the provisions of this chapter or (b) for failure to meet any of the rules and regulations with reference to equipment for the prescription department; stock of drugs, pharmaceuticals and chemicals in the prescription department; size and other space requirements of the prescription department; facilities necessary in the compounding of prescriptions; and sanitation, orderliness and cleanliness in the pharmacy or drug store, or (c) with respect to any pharmacy or drug store in which an offense subject to the provisions of section 30 of this amendatory and supplementary act has occurred, by serving a copy of the complaint upon the owner of the pharmacy or drug store and granting at least 10 days' advance notice of a hearing before the board. The suspension or revocation by the board of any permit issued by it shall be reviewable by a proceeding in lieu of the prerogative writs in the Superior Court.

L.1948, c. 105, p. 560, § 3, eff. May 28, 1948. Amended by L.1953, c. 43, p. 815, § 70, eff. March 19, 1953; L.1953, c. 279, p. 1813, § 1, eff. July 25, 1953; L.1966, c. 313, § 31, eff. Dec. 29, 1966.

45:14-36.4. Conduct of business during period of revocation forbidden

It shall be unlawful for any person, firm or corporation to operate, or conduct any business, in any pharmacy or drug store without a permit issued by the board or during the period of suspension of any permit theretofore issued for the operation of such pharmacy or drug store or any time after a permit theretofore issued for the operation of such pharmacy or drug store has been revoked. Any person, firm, or corporation found guilty of violating the provisions of this section shall be liable to a penalty of $100.00 for each day during which said violation continues to be sued for and recovered in the name of the board.

L.1948, c. 105, p. 561, § 4, eff. May 28, 1948. Amended by L.1970, c. 283, § 1, eff. Dec. 3, 1970.

45:14-37 to 45:14-39. Repealed by L.1979, c. 432, § 1, eff. Feb. 14, 1980

CHAPTER 39
STATE BOARD OF PHARMACY

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14-1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, supportive personnel and anyone within the jurisdiction of the Board of Pharmacy.

13:39-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Address of record'' means an address designated by a licensee which is part of the public record and which may be disclosed upon request. "Address of record'' may be a licensee's home, business or mailing address, but shall not be a post office box.

"Authorized prescriber'' means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

"Board'' means the New Jersey State Board of Pharmacy.

"Compounding'' means the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber's prescription or medication order, including, but not limited to prescription compounding, and intravenous admixture preparation.

"Device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

"Direct supervision'' means that the registered pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing of drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Dispense or dispensing'' means the procedure entailing the interpretation of an authorized prescriber's prescription order for a drug or device, and pursuant to that order, the proper selection, measuring, labeling, and packing in a proper container. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medicine'' means:

1. Articles recognized in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

3. Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and

4. Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

"Legend drug or device'' means any drug or device that:

1. Bears, at a minimum, the symbol "Rx only'' or words of similar import; and/or

2. Requires a prescription or order by an authorized prescriber.

"Licensed practitioner'' means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, nurse practitioner/clinical nurse specialist or physician assistant, or other health care practitioner licensed or approved to write prescriptions intended for the treatment or prevention of disease, as set forth in N.J.S.A. 45:14-14.

"Pharmaceutical services'' means all services provided by a registered pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labelling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counselling on the proper and safe use of drugs and medications.

"Prescription'' means any order for drugs and related items as defined in N.J.S.A. 45:14-14.

"Professional judgment'' means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the prescriber.

"Registered pharmacist'' or "pharmacist'' means a person whose license is in good standing for the current license renewal period.

"Supportive personnel'' means those persons who perform pharmaceutical functions under the direct supervision of a registered pharmacist. Interns and externs are specifically excluded from this definition.

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i. Application for registration .....$125.00.
ii. Examination: $50.00 plus the cost of the North American Pharmacist Licensure Examination (NAPLEX)
(1) Multistate Jurisprudence Pharmacy Examination (MJPE) $60.00
iii. Reciprocal fee 125.00
iv. Reinstatement of licensure .....225.00 plus application fee
v. Initial licensure fee
(1) If paid during the first year of a biennial renewal period 140.00
(2) If paid during the second year of a biennial renewal Period 70.00
vi. Biennial license renewal 140.00
vii. Replacement biennial license 25.00
viii. Transfer of grades 125.00
ix. Late renewal fee 100.00
x Replacement wall license 40.00
xi. Continuing education review fee 10.00
xii. Continuing education program: provider review fee 50.00
xiii. Yearly fee for distribution of minutes and agenda 60.00

2. For pharmacies as follows:
i. Pharmacypermits
(1) Application for permit 275.00
(2) Annual renewal 175.00
(3) Change of ownership 275.00
(4) Change of location 275.00
ii. Replacement permit certificate 25.00
iii. Replacement wall permit 25.00
iv. Late renewal fee 100.00

13:39-1.4 Payment of penalties

(a) Any penalties levied by the Board must be paid within 30 calendar days of the receipt of a penalty letter or final order of the Board unless otherwise prescribed by statute or terms of a final order.

(b) Failure to comply with this rule will result in action by the Board according to the provisions of N.J.S.A. 45:1-24.

13:39-1.5 Hearings

(a) Any time the Board seeks to impose a disciplinary sanction upon a licensee, the licensee may request a hearing.

(b) Any hearings held shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

SUBCHAPTER 2. APPLICANT QUALIFICATIONS AND EXAMINATIONS REQUIREMENTS

13:39-2.1 Examinations; grades

(a) The examination for licensure by the Board shall be the North American Pharmacist Licensure Examination (NAPLEX). An applicant shall attain a passing grade of not less than 75. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) The applicant shall also pass the Multistate Jurisprudence Pharmacy Examination (MJPE). A passing grade of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(c) If the applicant should fail either the NAPLEX or the MJPE three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the field examination(s).

13:39-2.2 Education requirements

(a) An applicant for the NAPLEX and MJPE examinations shall have been duly granted or have fully completed all the requirements for graduation of a minimum five-year pharmacy course leading to a degree of Bachelor of Science in pharmacy or Doctor of Pharmacy given in a school or college of pharmacy accredited by the American Council of Pharmaceutical Education (ACPE).

(b) Before being admitted to the examination, either a transcript of the applicant's record or a certificate by the registrar of the school or college of pharmacy attended must be supplied stating that the applicant has either graduated or has completed all of the requirements for graduation. If the transcript or certificate does not state that the applicant has graduated or
has completed all the graduation requirements, the Board may require other forms of proof to be supplied by the applicant.

13:39-2.3 Application to be filed

An applicant for the NAPLEX and MJPE examinations shall file an application for such examination at least 30-days prior to the date of the examination unless the 30 day requirement is waived by the Board because of extenuating circumstances. The required fees as prescribed in N.J.A.C. 13:39-1.3 shall also be submitted.

13:39-2.4 (Reserved)

13:39-2.5 (Reserved)

13:39-2.6 (Reserved)

13:39-2.7 Age requirement

An applicant who is not of legal age, that is, the age of majority in the State of New Jersey, but who has otherwise met the application requirements, with the exception of the internship requirement, may be admitted to the NAPLEX and MJPE examinations; however, the applicant shall not be eligible for licensure until attaining legal age.

13:39-2.8 Proof of character

(a) An applicant for the NAPLEX and MJPE examinations shall submit, in advance, an application containing evidence of good moral character which is an ongoing requirement for licensure, and evidence that he or she:

1. Is not a chronic or persistent inebriate;

2. Is not addicted to the use of any controlled dangerous substance or other habit-forming drug;

3. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;

4. Has not been convicted of violating the provisions of any law relating to the sale of liquors;

5. Has not been convicted of violating any law relating to the practice of pharmacy;

6. Has not been convicted of a crime involving moral turpitude; and

7. Has not had his or her license or, if a permit holder, his or her permit, suspended or revoked in the last five years as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

13:39-2.9 Proof of identity of applicant

An applicant for the NAPLEX and MJPE examinations must submit to the Board 30
days in advance of the date of the written examination a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

13:39-2.10 Alleged violations of the Pharmacy Act

If an applicant for any Board examination is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14-1 et seq., the Board in its discretion may deny the applicant the opportunity to take the examination.

SUBCHAPTER 3. LICENSURE OF PHARMACISTS

13:39-3.1 License

An applicant who has successfully passed all Board examinations shall receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice pharmacy in the State of New Jersey until such time as an initial license may be issued.

13:39-3.2 Duplicate license

A duplicate license may be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the original license or upon return of the damaged original license to the Board.

13:39-3.3 Change of name

If a registered pharmacist legally changes his or her name, the name change shall be recorded in the Board's records. The registered pharmacist shall submit original proof of the change of name or a certified copy of the court order or marriage certificate which will be retained by the Board. When a duplicate license is issued, the original license must be returned for cancellation along with the required fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-3.4 Change of address of record

A registered pharmacist shall notify the Board in writing of any change in his or her address of record within 30 days.

13:39-3.5 Certification of records

A certification that the license of a registered pharmacist is in good standing shall be supplied by the Board upon request.

13:39-3.6 Reproduction of original license prohibited

The original wall license, biennial license or wallet-sized license issued by the Board to any pharmacist shall not be reprinted, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, except as provided in N.J.A.C. 13:39-3.16.

13:39-3.7 Limitation of reciprocal licensure

(a) Reciprocal licensure of out-of-State pharmacists shall be limited to those pharmacists who have been duly licensed in mutually reciprocating states.

(b) Applicants who have graduated from pharmacy schools which have not been accredited by the American Council on Pharmaceutical Education but who have been licensed by the District of Columbia, a reciprocating state or a United States territory shall be eligible for transfer of licensure if the Board is satisfied that the licensing procedures applicable to graduates of non-accredited schools in a state of licensure are equivalent to the Board's standards for licensure at the time initial licensure was obtained.

13:39-3.8 Basic requirement for transfer of licensure

An applicant for reciprocal licensure in the State of New Jersey shall hold a current, valid license in any state of licensure, including the District of Columbia and territories of the United States, that has a standard for initial licensure that is equivalent to the standard of licensure that was in effect in the State of New Jersey at the time initial licensure was obtained.

13:39-3.9 Out-of-State practice requirement for transfer of license from a mutually reciprocating state

(a) An applicant for reciprocal licensure in the State of New Jersey shall be in good standing with any state in which the applicant is licensed and must have:

1. Practiced in pharmacy for at least 1000 hours within the two years immediately prior to application; or

2. Served a pharmacy practicum in New Jersey, in the presence of a New Jersey registered pharmacist approved by the Board as a certified preceptor pursuant to N.J.A.C. 13:39-8.2, of not fewer than 500 hours within the one year immediately prior to application.

13:39-3.10 Clear record of law observance

Eligibility for reciprocal licensure shall be denied any person against whom there are pending any formal charges for any violations of the laws governing the practice of pharmacy or the dispensing of controlled dangerous substances, alcohol or other regulated drugs, or who has been convicted of any crime within the past five years. All applicants for transfer of licensure shall meet the character requirements outlined in N.J.A.C. 13:39-2.8.

13:39-3.11 Foreign graduates

(a) Any pharmacist applicant with a degree from a country where the primary language is other than English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has been certified within two years of applying for licensure in the State by the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy.

(b) Any pharmacist applicant with a degree from a country other than the United States, where the primary language is English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(c) A request for waiver of the FPGEC certificate shall delineate good cause for the waiver request. The Board may, after due consideration and within its own discretion, waive the TOEFL examination and the Test of Spoken English (TSE) examination components of the FPGEC certification process.

13:39-3.12 Physical and mental competence of reciprocal licensees

(a) An applicant for reciprocal licensure shall be physically and mentally able to perform all duties normally required of a registered pharmacist.

(b) The Board, at its discretion, may require proof of the applicant's physical and mental competence to practice pharmacy in this State.

13:39-3.13 Preliminary application

A preliminary application obtained from the Board for reciprocal licensure shall be submitted to the National Association of Boards of Pharmacy.

13:39-3.14 Multistate Jurisprudence Pharmacy Examination: reciprocal licensure

(a) An applicant for reciprocal licensure shall pass the Multistate Jurisprudence Pharmacy Examination. A passing grade of not less than 75 shall be attained. If an applicant fails the examination, he or she will be required to repeat the examination.

(b) If the applicant for reciprocal licensure fails the examination three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the law examination.

13:39-3.15 Biennial license renewal

(a) Every registered pharmacist, on or before April 30 of each odd-numbered year, shall renew his or her license through the payment of a license renewal fee as prescribed by N.J.A.C. 13:39-1.3 and the filing of a renewal application.

(b) The renewal application shall list the name, home address, original license number, places and hours of employment, continuing education credits, and other information as requested.

(c) The renewal application shall be signed by the applicant.

13:39-3.16 Duplicate renewal license

If a renewal license is lost or destroyed, a duplicate renewal license may be obtained upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3. Proof of the applicant's identity and proof of loss or destruction of the applicant's renewal license originally issued must be submitted.

13:39-3.17 Reinstatement in good standing

(a) If a registered pharmacist permits his or her license to lapse for a period of less than five years through a failure to renew his or her license, the license may be brought into good standing through payment as per N.J.A.C. 13:39-1.3(a)1iv and vi of the reinstatement fee, the current and lapsed renewal fee(s) and any outstanding penalties and upon submission of proof of identity and the filing of an application to be obtained from the Board. An applicant for reinstatement shall also submit proof of satisfaction of continuing education requirements as provided in N.J.S.A. 45:14-11.11.

(b) If the license has lapsed for a period of five years or longer, the applicant for such reinstatement must pass the Multistate Jurisprudence Pharmacy Examination. The applicant shall also submit payment as per N.J.A.C. 13:39-

1.3(a)1iv and vi of the reinstatement fee and the current renewal fee and proof of identity along with an application to be obtained from the Board.

An applicant for reinstatement shall also submit proof of satisfaction of continuing education requirements as provided in N.J.S.A. 45:14-11.11.

(c) Every applicant for reinstatement must submit evidence of satisfactory completion of the continuing education requirements which are 15 credits per year up to a maximum of five years or 75 credits.

13:39-3.18 Registered pharmacist-in-charge

(a) A registered pharmacist shall not assume the responsibilities of a registered pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously.

(b) There shall not be more than one registered pharmacist-in-charge of any one pharmacy or pharmacy department.

(c) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, the incoming registered pharmacist-in-charge shall take an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5.

(d) Whenever a registered pharmacist assumes the duties of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, he or she shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(e) A registered pharmacist-in-charge shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to ensure the fulfilling of the following responsibilities:

1. Employment and supervising personnel in a prescription department or pharmacy department;

2. Maintaining accurate records of all prescription medication received and dispensed;

3. Ensuring that medication dispensed conforms with the prescription received;

4. Maintaining the security of the prescription area and its contents, which includes the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription area while the pharmacist is temporarily absent but within the premises;

5. Ensuring that only pharmacists and interns or externs under direct supervision provide professional consultation with patients and physicians;

6. Ensuring that only pharmacists, interns or externs accept telephone prescriptions and renewal authorizations;

7. Ensuring that all dispensed medication is properly labeled;

8. Ensuring the use of prescription labels naming the registered pharmacist-in-charge;

9. Ensuring the posting of the name of the registered pharmacist-in-charge on the entrance to the pharmacy or pharmacy department in such a way as to be visible to the public;

10. Prohibiting the presence of misbranded, deteriorated or outdated drugs in the active stock in the pharmacy;

11. Operating the prescription area in an orderly and sanitary manner;

12. Ensuring the dispensing of all medication generally prescribed to patients in the trading area of the licensed premises or as required by the speciality for which the pharmacy holds a permit;

13. Notifying the Board in writing within 30 days when his or her duties as registered pharmacist-in-charge terminate at a specific location; and

14. Ensuring compliance with all statutes, rules and regulations governing the practice of pharmacy.

SUBCHAPTER 4. PHARMACY PERMITS

13:39-4.1 Issuance of permits

All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

13:39-4.2 Display of permits

A permit issued by the Board for the operation of a pharmacy or other licensed establishment shall be conspicuously displayed.

13:39-4.3 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall apply immediately for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39-1.3.

13:39-4.4 Change of ownership

Whenever there is any change in ownership of the business entity holding a permit to operate a pharmacy, the new ownership of such entity shall apply for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39-1.3. The new owner of such entity shall not operate a pharmacy under an existing permit for more than 60 days following a change in ownership. Before a permit may be issued to the new owner of the business entity, the Board shall inspect and approve, as in compliance with this chapter, the fixtures, equipment and inventory of the pharmacy, and shall require evidence of the transfer of ownership and an inventory of controlled substances being transferred to the new owner(s).

13:39-4.5 Change of corporate officers or stockholders of public companies

If there is a change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock, the corporation shall file an affidavit with the Board within 30 days indicating the changes that have taken place and any other information requested by the Board.

13:39-4.6 Change of location; remodeling of premises

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply for a new permit on a form prescribed and furnished by the Board. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39-1.3. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following a change of location. Before a permit may be issued to the permit holder for the new location, the Board shall inspect and approve, as in compliance with this chapter, the premises, fixtures, equipment and inventory of the new location.

(b) Prior to the remodeling of a pharmacy, pharmacy department or licensed establishment, where such remodeling entails a physical change of location of the prescription area within the premises or a change of the physical specifications of the licensed premises or the compounding area, it shall be necessary to notify the Board at least 30 days in advance on a form prescribed
by the Board. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following the remodeling of a pharmacy. Within 60 days of the remodeling, the Board shall inspect and approve, as in compliance with this chapter, the premises, fixtures, equipment and inventory of the remodeled pharmacy.

13:39-4.7 New pharmacies; eligibility and application

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship or partnership; the names and addresses of all officers and stockholders and the names and addresses of all principles duly licensed to write prescriptions if the pharmacy is a non-publicly held corporation; and the names and addresses of the officers, if a publicly held corporation.

(d) The permit application shall include the name of the registered pharmacist-in-charge who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person or other business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, state or Federal law pertaining to the practice of pharmacy or the dispensing of controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Before a permit may be issued to an applicant, the Board shall inspect and approve, as in compliance with this chapter, the premises, fixtures and equipment of the new pharmacy.

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

13:39-4.8 Discontinued pharmacies

(a) Whenever a pharmacy is terminated by suspension, retirement or death of the owner, sale or other cause including insolvency, all drug signs shall be removed from both the inside and outside of the discontinued pharmacy, and the permit shall be returned to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39-5.6.

(b) Whenever a pharmacy is to be discontinued, it shall be the responsibility of the permit holder to immediately notify by telephone the State Board of Pharmacy, the Drug Control Program in the State Department of Health and the Drug Enforcement Administration of the proposed closing at least 15 days beforehand, followed by a letter in writing to those agencies. All medication (both prescription legend and controlled drugs) shall remain on the licensed
pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the above agencies.

13:39-4.9 Business hours

(a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

(b) If any changes are made in the opening or closing hours of a pharmacy or other Board-licensed establishment, the Board office shall be notified in writing of these changes within 30 days.

13:39-4.10 Duplicate permit

A duplicate permit may be issued by the Board upon payment of a fee pursuant to N.J.A.C. 13:39-1.3 and submission of an affidavit describing the loss or destruction of the permit originally issued, or upon return of the damaged permit.

13:39-4.11 Change of name

(a) A change in the name of a pharmacy or other Board-licensed establishment shall be made upon the submission to the Board for approval of the new name and of prescription labels bearing the new name.

(b) An amended permit bearing the new name may be obtained upon return of the original permit to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.12 Reproduction of permits

Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment, with the exception of single copies to State agencies shall not be printed, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, without the express authorization of the Board.

13:39-4.13 Certification of records

A certification of any of the information not obtained by the Board on a confidential basis, which appears in the Board records and concerns the ownership or registration of a pharmacy or other Board-licensed establishment, will be supplied only upon written request and payment of a certification fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.14 Contract pharmaceutical services

An institutional permit is required for any area within an institution where drugs are stored, manufactured or compounded and which is serviced by an outside vendor that performs pharmaceutical services as defined in N.J.A.C. 13:39-1.2.

13:39-4.15 Retail permit; prescription department or pharmacy department

(a) If the area for which a pharmacy permit is sought is less than the total store area of the enterprise, the area subject to permit shall be known as the "Prescription Department'' or "Pharmacy Department''.

(b) The holder of a permit to operate a prescription or pharmacy department and the registered pharmacist-in-charge of the department shall be subject to the following additional requirements:

1. The prescription or pharmacy department shall be constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto. Any entrance to the prescription or pharmacy department shall be capable of being locked and connected to a security device or other Board approved security system.

2. The registered pharmacist on duty shall be responsible for keeping the prescription department secure and locked and the alarm system turned on at all times when he or she does not have full vision or control of the department or when he or she is not present within the department. Only the registered pharmacist-in-charge of the licensed premises shall be responsible for the security of the keys to the department.

3. No prescription shall be accepted or prescription medication supplied to anyone during the period that a registered pharmacist is not present within the department.

4. All medications requiring supervision of a pharmacist, including dispensed medication, shall remain within the confines of the department when the pharmacist is not in the prescription department.

5. The hours that the department is open shall be posted in plain view at the entrance to the department and at the public entrance to the enterprise containing the department.

6. When the enterprise in which the department is located maintains different store hours from the pharmacy or prescription department, all advertising, announcements, signs or statements indicating store hours and the presence of the pharmacy or prescription department shall clearly and distinctly indicate the hours that the department is open.

7. The prescription department shall have a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department.

8. The name of registered pharmacist-in-charge shall be posted so as to be visible from outside of the department. The telephone number of the registered pharmacist-in-charge shall be available in the office of the manager of the establishment.

9. There shall be provided a secure area for the receiving of prescription drugs from suppliers. No prescription drug shall be accepted from any supplier during the hours the prescription or pharmacy department is closed unless adequate security for the storage of department shipments has been provided and approved by the Board.

10. If a drop-off device is utilized for prescriptions it shall be of a one-way, irretrievable design.

13:39-4.16 Permits; specialized permits

(a) The Board may issue a special permit, wherein the type of service is of a limited nature. The permit so issued, being based on special conditions of use imposed by the Board, may necessitate the waiver of certain rule requirements.

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized
pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

13:39-4.17 Steering prohibited

It shall be unlawful for a pharmacist or a pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or with any health care facility for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient’s freedom of choice to select a pharmacy.

13:39-4.18 Responsibilities of pharmacists and permit holders

(a) All pharmacists and all permit holders are responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any pharmacist and any permit holder may be held liable for violations of the Act and these rules and may be subject to disciplinary action.

SUBCHAPTER 5. PRESCRIPTIONS

13:39-5.1 Imprinted prescription blanks

No prescriber's prescription blanks shall bear the imprint of the name of any pharmacy or other licensed premises or bear the name and address of any person registered under N.J.S.A. 45:14-1 et seq.

13:39-5.2 Lack of directions on original prescription

(a) If the prescriber fails to include on the original prescription directions to the patient for use of the medication, the registered pharmacist shall make a documented attempt to contact the prescriber to obtain such directions. In cases where the prescriber cannot be contacted, the registered pharmacist shall indicate on the label the words "use as directed'' or "as ordered by
the physician'' or similar words to the same effect.

(b) When, in the judgment of the pharmacist, directions to the patient or cautionary messages are necessary, either for clarification or to ensure proper administration of the medication, the pharmacist may add such directions or cautionary messages to those indicated by the prescriber on the original prescription.

13:39-5.3 Authorization for renewal of prescriptions

(a) A prescription for medication or devices which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber, and the prescription may not be refilled after one year from the date of original prescription.

1. Prescriptions marked "PRN'' or other letters or words meaning refill as needed shall not be renewed beyond one year past the date of original prescription.

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the prescriber as provided in N.J.S.A. 45:14-14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

13:39-5.4 Approval of FDA necessary

No drug or medicine other than a compounded prescription order shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received an approved NDA, ANDA, INDA or other Federal Food and Drug Administration approval.

13:39-5.5 Copies of prescriptions; transfers

(a) Copies of prescriptions issued directly to the patient by the pharmacy where the medication was dispensed, pursuant to the receipt of the prescription, shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY FOR INFORMATION ONLY.'' A pharmacist shall immediately comply with the patient's request for copies of prescriptions that are marked: "COPY FOR INFORMATION ONLY.''

(b) Presentation of a prescription label or a prescription marked "COPY FOR INFORMATION ONLY'' shall be for information purposes only and have no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner or transferor pharmacy and obtain all information required by (c)2 below for authorization to dispense the prescription, which is the same as obtaining an original prescription order.

(c) A copy of a prescription may be transferred by telephone or electronic transfer by pharmacists between pharmacies for the purpose of refill dispensing provided that:

1. The transferor pharmacist invalidates the prescription on file as of the date the copy is transferred by writing "VOID'' on its face, and records on the back of the invalidated prescription order that a copy has been issued, the date of issuance of such copy, to which pharmacy and pharmacist, and the initials of the pharmacist issuing the transferred prescription order.

2. The transferee pharmacist, upon receiving such prescription directly from another pharmacist, records the following:

i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;

ii. The name of the transferor pharmacist;

iii. All information constituting a prescription order, including the following:

(1) Date of issuance of original prescription;

(2) Original number of refills authorized on original prescription;

(3) Complete refill record from original prescription;

(4) Date of original dispensing;

(5) Number of valid refills remaining.

3. The transferee pharmacist informs the patient that the original prescription has been cancelled at the pharmacy from which it was obtained.

(d) When a copy of a prescription is issued by telephone, refill authorizations shall be cancelled on the original prescription and the fact that a copy has been issued shall be noted on the original prescription along with the date the copy was issued. Two or more permit holders may establish a common electronic filing system to maintain required dispensing information and the required documentation, pursuant to N.J.A.C. 13:39-5.6.

(e) When a patient, or his or her properly authorized representative, requests the transfer of a valid prescription between pharmacies, a pharmacist shall immediately comply with the patient's request. "Properly authorized representative'' means a patient's spouse, next of kin, legal guardian, attorney or third party insurer where permitted by law.

13:39-5.6 Record of pharmacist filling prescription

(a) A registered pharmacist who fills or compounds a prescription or who supervises the filling or compounding of a prescription by an intern or extern shall place his or her signature or readily identifiable initials on the face of the original prescription. In using an electronic data processing system, the initials of the pharmacist responsible for the filled prescription shall also be recorded.

(b) A registered pharmacist who refills a prescription shall place his or her signature or readily identifiable initials on the reverse side of the original prescription next to the date of the refill and the amount dispensed in refilling the prescription if it is different from the original amount prescribed. In using an electronic data processing system, the identical refill information shall also be recorded.

(c) A record identifying such initials with the signature and name and address of the pharmacist shall be maintained for a period of five years after the termination of employment of said pharmacist.

(d) Prescriptions for all controlled substances listed in schedule II shall be maintained in a separate prescription file.

(e) Except when they are kept in a separate file, prescriptions for all controlled substances listed in schedules III, IV and V shall be stamped in red ink in the lower right corner with the letter "C" no less than one-inch high.

(f) Prescriptions for all controlled substances listed in schedules III, IV and V shall be maintained in a single file separate from all other prescriptions, unless an electronic data processing system is utilized which meets the requirements of (i) below. If such an electronic data processing system is utilized, prescriptions for all substances listed in schedules III, IV and V shall be filed either in the prescription file for controlled substances listed in schedule II or in the usual consecutively numbered prescription file for noncontrolled substances.

(g) If an electronic data processing system is utilized in connection with the dispensing of medication and the required recording of prescription information, a means acceptable to the Board shall be utilized to identify the pharmacist or intern or extern dispensing the medication.

(h) In using an electronic data processing system, the pharmacist in charge shall maintain a document log. The document log shall be maintained at the pharmacy for a period of five years after the date of the last entry. The five years of record information, including refills, shall be kept in such a manner as to be sight-readable within two weeks. The most recent one year of record information shall be immediately retrievable.

(i) In using an electronic data processing system, the system shall have the capability of producing sight-readable documents of all original and refilled prescription data, and, in addition, the number of refills authorized by the prescriber for a period of not less than five years. Five years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of record information shall be immediately reviewable on-line and available in printed form within three business days. The term "sight-readable", as it appears in all rules of the Board, shall mean that the Board or Attorney General shall be able to examine and read the record of information. During the course of an on-site inspection, the record may be read from a cathode ray tube (CRT), microfiche, microfilm, hard copy printout or other Board acceptable method. For the purpose of administrative proceedings before the Board, records shall be provided in a paper printout form.

(j) Initials and/or access code number(s) of the dispensing pharmacist and intern or extern, if applicable, shall be entered into the system each time a prescription is filled or refilled. Computer programs which automatically generate a pharmacist's initials without requiring a direct entry by the dispensing pharmacist at the time of dispensing are prohibited.

13:39-5.7 Availability of records upon termination of business

(a) Where a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the licensee, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons of their right to retrieve currently valid prescriptions and the location of the prescriptions and profile records for a six-month period following notice, using all of the following methods:

1. Notification in writing to the Board;

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major area of the licensee's former practice, of a notice advising patrons of the right to retrieve their prescriptions and the location of the prescriptions for a six-month period following publication; and

3. A sign placed in the pharmacy location informing the patrons of the right to retrieve their prescriptions and the location of the prescriptions.

13:39-5.8 Prescriptions and medication orders transmitted by technological devices

(a) A pharmacist may, subject to the conditions set forth in this section, accept for dispensing a prescription or a medication order transmitted by a facsimile (FAX) machine or other technological device as approved by the Board.

(b) A registered pharmacist at a retail pharmacy and a registered pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for out-patients who are treated by staff members of the institution in their respective clinics, as permitted pursuant to N.J.S.A. 45:14-32, may accept for dispensing prescriptions for all substances other than Schedule II controlled dangerous substances which have been transmitted by technological device, under the following conditions only:

1. Before releasing to other than an in-patient of a health care facility, as defined in N.J.A.C. 13:39-9.1, any prescription medication for a controlled dangerous substance listed in Schedules III, IV or V, the pharmacist shall obtain and file the original signed prescription.

2. The pharmacist shall, within 24 hours, reduce to hard copy, that is, record in his or her handwriting or enter into a computer, all prescriptions received by technological device other than prescriptions for Schedules III, IV and V controlled dangerous substances and shall place the copy in the permanent prescription file records.

(c) A registered pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39-9.1, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device. Medication orders for narcotic Schedule II controlled substances written for long-term care facility residents or hospice patients, which are transmitted by facsimile, shall serve as the original written medication orders, in accordance with the provisions of 21 C.F.R. 1306.11(d), (e), (f) and (g).

(d) Whenever a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted by technological device, the pharmacist shall verify the transmission directly with the prescribing practitioner.

(e) It shall be deemed professional misconduct for a pharmacist to use a technological device in order to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or in order to circumvent other standards of pharmacy practice.

(f) No licensee or permit holder registered under N.J.S.A. 45:14-1 et seq. shall under any circumstances provide a technological device to, or accept a technological device from, any practitioner licensed to write prescriptions.

(g) No licensee or permit holder shall enter into any agreement with an authorized practitioner which denies the patient the right to have his or her prescription transmitted by technological device to a pharmacy of the patient's choice.

13:39-5.9 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following information:

1. The name of the registered pharmacist-in-charge;

2. The pharmacy name and address;

3. The pharmacy telephone number;

4. The brand name or generic name;

i. If generic, the name of the manufacturer;

5. The date upon which prescription medication is dispensed;

6. A CDS cautionary label;

7. The patient name;

8. The initials of dispensing pharmacist;

9. The prescriber's name;

10. The prescription number;

11. Directions for use; and

12. The expiration date, if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "expiration date'' means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

(b) In addition to the requirements set forth in (a) above, the dispense container for any product shall bear all auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist.

SUBCHAPTER 6. DISPENSING AND ADVERTISING DRUGS

13:39-6.1 Professional judgment in dispensing drugs

(a) The pharmacist shall have the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of practice of the prescriber; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient.

(b) A pharmacist may dispense an emergency supply (no more than a 72-hour quantity) of a chronic maintenance drug (except controlled dangerous substances) or device in the absence of a current valid prescription, if, in his or her professional judgment, refusal would endanger the health or welfare of the patient.

1. The pharmacist must first ascertain to the best of his or her ability, by direct communication with the patient, that such a medication or device was prescribed for that patient by order of a licensed practitioner.

2. The pharmacist shall document the communication and require the patient to provide suitable identification and sign a statement attesting to the need before dispensing.

3. A patient's signature is not required for emergency refilling of a previously valid prescription.

13:39-6.2 Prescription prepared, compounded or dispensed by pharmacy externs or interns

A pharmacy intern or extern may prepare, compound or dispense prescriptions only under the direct supervision of a registered pharmacist of this State.

13:39-6.3 Identification tag

Each licensee shall wear an identification tag which shall include at least the pharmacist's first name, the first initial of his or her last name, and the designation "Pharmacist.''

13:39-6.4 Direct supervision of dispensing and compounding

The registered pharmacist supervising the activities of supportive personnel shall be physically present in the compounding/dispensing area and shall be personally responsible for the accuracy of the filled prescription.

13:39-6.5 Restriction on display of prescription legend drugs and controlled dangerous substances

Prescription legend drugs, devices and controlled dangerous substances shall not be displayed in the licensed establishment in such a manner that they can be accessible to the public.

13:39-6.6 Foreign prescriptions

Only those prescriptions written or signed by an authorized prescriber licensed to write prescriptions in the United States, District of Columbia, or any territory of the United States shall be considered valid prescription orders.

13:39-6.7 Supportive personnel

(a) Supportive personnel may assist the registered pharmacist in a clerical manner such as the retrieving of prescription files, profile cards, and other such records, the typing of labels and the completing of prescription receipts and other such forms.

(b) Supportive personnel shall not interpret a prescription order or consult with a patient or prescriber or the agent of the prescriber. Supportive personnel may, however, count, weigh, measure, or pour prescription medication under the direct supervision of the registered pharmacist as long as the contents and finished-product are verified by a registered pharmacist.

(c) There shall be no more than two supportive personnel, not including cashier, stocking and clerical help, being supervised by one pharmacist at any given time. Those personnel who do computer processing of prescriptions are to be included in the 2 to 1 ratio.

(d) Supportive personnel shall wear an identification tag, which shall include at least their first name, the first initial of their last name, and title.

(e) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all supportive personnel which it currently employs.

(f) When supportive personnel are engaged in any activity permitted by (b) above, the supervising registered pharmacist shall be responsible for all the activities of the supportive personnel.

13:39-6.8 Advertising and sale of prescription drugs

(a) "Advertisement'' means any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media which directly or indirectly induces or attempts to induce any person or entity to purchase or enter into an agreement to purchase services or goods from a Board licensee.

(b) Price quotations for prescription drugs appearing in any advertisement shall stipulate the strength and quantity required to be purchased for the offered cost. Price quotations shall include the usual and customary prescription cost. All services including, but not limited to, delivery charges rendered by the pharmacy which will add additional costs to the price quoted, must be set forth in the advertisement.

(c) Any reference in any form of advertisement to the quality of a drug or its beneficial use is prohibited.

(d) Price quotations for drugs appearing in any advertisement shall stipulate the effective period of price quotation.

(e) Upon request by any consumer, the pharmacist shall be required to give price information over the telephone and shall stipulate the effective period of the price quotation.

(f) All advertisements shall be predominantly informational and shall not be misleading, confusing or false. Any advertisement demeaning the quality of professional services rendered by another licensee or permittee shall be prohibited. No advertisement shall rely in any way on techniques to obtain attention that demonstrate a clear and intentional lack of relevance to the selection of professional services.

13:39-6.9 Restriction on sale of Schedule V over-the-counter controlled substances

(a) It shall be considered unprofessional conduct for a pharmacist to dispense a Schedule V over-the-counter controlled substance when:

1. The pharmacist, in his or her professional judgment, knows or reasonably should know that the requested substance will be used for unauthorized or illicit consumption or distribution; or

2. The pharmacist, in his or her professional judgment, knows or reasonably should know that the person requesting the substance previously used it for unauthorized or illicit consumption or distribution.

(b) The standard of professional judgment and care that attends the sale of a Schedule V over-the-counter controlled substance shall conform to the following:

1. All pharmacists shall comply with N.J.A.C. 8:65-7.19, which requires that the sale of specified controlled substances be limited in quantity during any 48-hour period, that the purchaser be at least 18 years of age, and that the pharmacist obtain suitable identification (including proof of age where appropriate) from every purchaser not known to the pharmacist.

2. In all instances, any doubts regarding the propriety of a sale of a Schedule V substance shall be resolved against making the sale.

3. The pharmacist shall enter every sale of a Schedule V substance in the Over-the-Counter Schedule V Record Book pursuant to N.J.A.C. 8:65-7.19. The information to be recorded shall include the purchaser's first and last name, street address, city and state, the name and quantity of the Schedule V substance sold, the date of each sale, and the name or initials of the pharmacist making the sale.

4. Upon an individual's second request for a Schedule V substance within a short period of time (two to four days), the pharmacist shall determine, through direct communication with the purchaser, whether the substance is being used correctly. In that regard, the pharmacist shall ascertain how many people are using the substance and whether the condition which the substance is being used to treat is improving.

5. Upon an individual's third request for a Schedule V substance within a short period of time relative to the number of persons using it (two to four days subsequent to the second purchase), the pharmacist shall advise the purchaser of the substance's abuse potential and shall caution the purchaser to consult a physician if the condition for which the substance is being used does not improve.

6. Upon an individual's fourth request for a Schedule V substance within a short period of time (two to four days subsequent to the third purchase), the pharmacist shall determine, through direct communication with the purchaser, how many people are using the substance, whether continued use will be therapeutic, whether the purchaser is treating a condition which requires a physician's consultation, whether the purchaser is exhibiting signs of drug abuse and whether the purchaser is making similar requests of other local pharmacies.

7. If a pharmacist determines that an individual's request for a Schedule V substance within a short period of time (two to four days) subsequent to his or her fourth purchase is warranted, the pharmacist shall document in the Over-the-Counter Schedule V Record Book the justification for such sale. In addition, the pharmacist shall recommend that the purchaser consult with a physician for medical evaluation due to the substance's abuse potential as well as the potential hazard presented by the substance's continued use.

8. If any Schedule V substance is dispensed to one individual more than five times within any 12-month period, the pharmacist shall obtain oral or written confirmation from the purchaser's physician as to the continued need for the substance and shall document such confirmation in the Over-the-Counter Schedule V Record Book.

SUBCHAPTER 7. PHARMACY FACILITY AND RECORDS

13:39-7.1 Retail pharmacy access and egress

Retail pharmacies shall be required to maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must traverse or traffic through any enterprise in which prescriptions are generated.

13:39-7.2 Retail pharmacy signs

Retail pharmacies shall be required to post a sign on the exterior of the building or a sign which is otherwise visible from a public roadway, conspicuously identifying the existence of a pharmacy on the premises, unless prohibited by lease agreement. In such case, a copy of the lease must be furnished to the Board.

13:39-7.3 Spatial requirement of a retail pharmacy prescription area

(a) For pharmacies in operation prior to July 1, 1963, the space devoted to the prescription area and laboratory shall not be less than 10 percent of the main floor area of the pharmacy or drugstore, and in no instance shall it be less than 50 square feet. If the main floor area of such pharmacy exceeds 1,200 square feet, the 10 percent requirement does not apply and the minimum requirement for the prescription area shall not be less than 120 square feet.

(b) For all other retail pharmacies including pharmacies subject to the provisions of (a) above which are moving to a new location, the prescription area must occupy exclusively a minimum of 150 square feet.

13:39-7.4 Prescription counter

There shall be a prescription counter or counters on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the compounding of prescriptions and other pharmaceutical manufacturing.

13:39-7.5 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area of retail and institutional pharmacies, easily accessible to the prescription counter. A similarly equipped sink shall be easily accessible to institutional satellite pharmacies as well as institutional and retail pharmacy intravenous admixture anterooms.

13:39-7.6 Storage and adequate stock

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, an adequate stock of prescription drugs and chemicals and the required equipment.

(a) The following minimum amount of equipment and facilities shall be required to be in every prescription area, and this equipment shall be stored so as to be readily accessible and shall be kept in a clean condition:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. Over the counter Schedule V Record Book, if Schedule V medication is sold without a prescription;

3. Permanent prescription filing device and patient profile record system;

4. Properly safeguarded storage place for Schedule II controlled substances if not dispersed;

5. Class A prescription balance or equivalent electronic weighing device;

6. Set of metric weights;

7. Devices capable of measuring 0.3 ml to 500 ml;

8. A glass mortar and pestle;

9. Glass funnels;

10. Stirring rods;

11. A steel spatula and a spatula of rubber or composition;

12. Ointment tile or parchment paper;

13. Refrigerator, as required by United States Pharmacopoeia Standards, to be used only for the storage of pharmaceuticals;

14. Suitable counting trays or approved counting device;

15. Labels;

16. Auxiliary labels, including poison labels;

17. Suppository mold; and

18. Two Drug Utilization Review Council Placards and the current Drug Utilization Review Council Formulary.

13:39-7.8 Cleanliness, orderliness and sanitation

The entire prescription area shall at all times be kept in a clean, orderly and sanitary condition.

13:39-7.9 Television in prescription area prohibited

No commercial television, other than for security measures, pharmacy training or patient counseling, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

13:39-7.10 Return of prescription medication

(a) No prescription medication shall be placed in stock for reuse or resale which has been returned after dispensing to a patient, except as provided in N.J.A.C. 13:39-9.15(a)2.

(b) Notwithstanding the provisions of (a) above, prescription medication incorrectly dispensed to a patient shall be accepted for return by the pharmacist and shall not be placed back in stock for reuse or resale.

13:39-7.11 Prescription balances, scales, weights and automatic counting devices

All pharmacies shall prove to the satisfaction of the Board that all balances, scales, weights and automatic counting devices have been annually inspected by the Department of Weights and Measures of the municipality or county in which such pharmacy, drugstore, or other Board-licensed establishment is located, and that such balances, scales, weights and automatic counting devices have been properly sealed by the applicable authority.

13:39-7.12 Disposal of unwanted drugs

Unwanted drugs shall be disposed of in a manner that does not cause them to become a health hazard, and in accordance with all local, State, and Federal codes.

13:39-7.13 Outdated drugs or drugs marked “sample’’

No outdated, misbranded, deteriorated or adulterated drugs, or any drugs marked “sample’’ or with any like designation or meaning shall be placed or maintained in active stock for use or sale.

13:39-7.14 Patient profile record system

(a) A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) shall be devised so as to enable the immediate retrieval of information

necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record may be maintained for members of a family living at the same address and possessing the same family name.

(b) The following information shall be recorded in the PPRS:

1. The family name and the first name of the person for whom the medication is intended (the patient);

2. The address and telephone number of the patient;

3. Indication of the patient's age, birth date or age group (infant, child, adult) and gender;

4. The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other Board-approved record;

5. The number or designation identifying the prescription;

6. The prescriber's name;

7. The name, strength and quantity of the drug dispensed; and

8. Pharmacist's comments relevant to the patient's drug therapy, including any failure of the patient to accept the pharmacist's offer to counsel.

(c) The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any medical conditions which may relate to drug utilization, as communicated to the pharmacist by the patient.

1. If there are no patient allergies, idiosyncrasies or medical conditions which may relate to drug utilization, the pharmacist shall so indicate on the patient profile record system.

(d) The pharmacist shall use professional judgment to review and monitor the patient profile, determine if there should be any adjustment in the original patient information and so indicate the appropriate change in the patient profile record.

(e) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record either in a manual or electronic data processing system before dispensing the medication, to determine the possibility of a potentially significant drug interaction, reaction or misutilization of the prescription. Upon determining a potentially significant drug interaction, reaction or misutilization, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the prescriber.

1. Except as set forth in (e)5 below, before dispensing a new prescription, the pharmacist shall make reasonable efforts to counsel the patient or caregiver. Counseling may, but need not, include the following:

i. The name and description of the medication;

ii. The dosage form, dosage, route of administration, and duration of drug therapy;

iii. Special directions and precautions for preparation, administration and use by the patient;

iv. Common adverse or severe side effects or interactions and contraindications that may be encountered, including their avoidance, and the action required if they occur;

v. Techniques for self-monitoring drug therapy;

vi. Proper storage;

vii. Prescription refill information; and

viii. Action to be taken in the event of a missed dose.

2. The offer to counsel may be made by ancillary personnel. However, counseling may be performed only by the pharmacist.

3. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

4. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be
available at no cost to the pharmacy's primary patient population.

5. The requirements to counsel the patient or caregiver upon receipt of a new prescription, as set forth in (e)1 through 4 above, shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24 hour nursing care.

6. Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the reasonable and prudent pharmacist's professional judgment, has elapsed from the last filling. When necessary, the pharmacist shall consult with the prescriber and/or the patient to assure himself or herself that continued use is appropriate.

7. When patient profile records indicate sporadic, erratic or irrational use of medication by a patient, the pharmacist shall consult with the patient and/or the prescriber to determine if continued use is appropriate.

8. All prescription patients who patronize a pharmacy shall have a profile record as specified by this section, and the pharmacist shall inquire as to whether other prescription drugs are being concomitantly utilized in order to establish a current drug history for the patient.

9. All of the foregoing assumes the patient is willing and capable of participating in his or her own plan of care.

(f) A patient profile record must be maintained for a period of not less than five years from the date of the last entry in the profile record. The oldest four years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of a record information must be immediately retrievable.

(g) If the pharmacy uses an electronic data processing system, an auxiliary recordkeeping system shall be established when the electronic data processing system is inoperative for any reason. When the electronic data processing system is restored to operation, the patient profile information and number of refills authorized during the time the electronic system was inoperative shall be entered into the electronic data processing system within 72 hours.

(h) If an electronic data processing system is used, the system shall provide adequate safeguards against manipulation and alteration of records and to protect confidentiality of the information contained in the data bank.

(i) The holder of the pharmacy permit shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(j) Failure to comply with this section shall subject the pharmacist to disciplinary sanctions.

SUBCHAPTER 8. PHARMACY TRAINING SITES

13:39-8.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Certified preceptor'' means a pharmacist registered in this State who assumes the responsibility to supervise and tutor a pharmacy intern or extern as outlined in N.J.A.C. 13:39-8.2.

"Faculty preceptor'' means a member of the faculty at an American Council of Pharmaceutical Education approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and tutor a pharmacy extern as outlined in N.J.A.C. 13:39-8.2.

"Pharmacy intern'' means any person who has graduated from an American Council of Pharmaceutical Education approved school or college of pharmacy, or if a foreign pharmacy graduate, any person who has satisfied the requirements of N.J.A.C. 13:39-3.11, who is employed in an approved training pharmacy for the purpose of acquiring accredited practical experience and who has first registered for said purposes with the Board.

"Pharmacy extern'' means any person who is in the fifth or sixth college year (or third or fourth professional year) at an American Council of Pharmaceutical Education approved school or college of pharmacy who is assigned to a training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she
is enrolled.

"Pharmacy internship or externship'' shall mean the program of acquiring practical experience by a pharmacy intern or extern respectively.

"Pharmacy training site'' means a site which satisfies the requirements of N.J.A.C. 13:39-8.3.

13:39-8.2 Preceptor certification application; procedures; responsibilities

(a) A registered pharmacist who wishes to be a certified preceptor shall apply to the Board and shall furnish evidence that he or she:

1. Has been registered and employed as a pharmacist in the area of practice in which he or she is to be engaged as a preceptor, on a full-time basis for at least two years in the State of New Jersey; and

2. Has a record of law observance.

(b) The Board shall approve a certified preceptor selected by each pharmacy intern, prior to the beginning of the internship. At no time may one certified preceptor supervise the training of more than one pharmacy intern.

(c) The certified preceptor in a pharmacy training site or a faculty preceptor shall report to the Board upon request on the progress and aptitude of any pharmacy intern or extern under his or her supervision.

(d) The compounding and dispensing of all prescriptions and drugs by the pharmacy intern or extern must be done under the direct supervision of a registered pharmacist.

(e) The certified preceptor or faculty preceptor is charged with the responsibility for the following:

1. Supervising the activities of the pharmacy intern or extern and ensuring that the intern or extern will keep abreast of developments in pharmacy by reading current professional literature and journals and by attending seminars and meetings of professional and scientific organizations; and

2. Providing the pharmacy intern or extern with experience and knowledge related to the preceptor's area of practice.

13:39-8.3 Pharmacy training site requirements

(a) To serve as a training site for interns, a pharmacy shall meet the following requirements:

1. Have a satisfactory record of observance of Federal, state and municipal laws and ordinances governing the activity in which it is or has been engaged.

2. Have a total number of prescriptions or medication orders filled annually, including renewals, of at least 20,000, with no more than one pharmacy intern or extern in training for each 20,000 prescriptions filled in the pharmacy.

3. Establish and maintain as part of the service it renders, a medication recordkeeping system for its patients that is approved by the Board.

4. Have available a reference library for use by the pharmacy intern.

(b) Notwithstanding the provisions of (a) above, a pharmacy which does not dispense medications but which serves as a pharmacy training site shall not be required to satisfy the requirements of (a)2 and 3 above.

13:39-8.4 Internship and externship practical experience

(a) The minimum accredited internship and externship practical experience requirement shall be the equivalent of 1,000 hours as follows:

1. One thousand hours for completion of a structured internship conducted after graduation from an accredited college of pharmacy and consisting of no less than 24 weeks supervised by a certified preceptor. Each week of practical experience shall consist of no less than 20 hours and no more than 45 hours of actual service per week. If the intern is a foreign pharmacy
graduate, he or she must have met all of the requirements of the National Association of Board of Pharmacy Foreign Pharmacy Graduate Examination Commission.

2. The certified preceptor and the pharmacy intern shall keep accurate records of the time spent by the pharmacy intern for credit toward the requirements of (a)1 above. The Board shall provide appropriate forms to be submitted to the Board for approval of postgraduate practical experience.

3. No credit shall be given for hours served as an intern prior to the Board's receipt of the written application.

(b) In lieu of the requirements set forth in (a)1 above, an applicant may obtain up to 1,000 hours practical experience by completion of a structured, college-credited externship and clinical pharmacy clerkship program of an accredited college of pharmacy. Such programs shall first be approved by the Board.

(c) In cases of a structured, college-credited externship and clinical pharmacy clerkship program, where less than 1,000 hours are accepted and approved by the Board, the balance of hours to make a total of 1,000 shall be gained through completion of a structured internship, conducted after graduation from an accredited college of pharmacy and supervised by a
certified preceptor with each week of practical experience consisting of no less than 20 hours and no more than 45 hours of actual service per week.

(d) A Board-approved college of pharmacy externship program shall provide that no less than 75 percent of the hours credited toward the practical experience requirement of the Board be gained in settings in which there is direct involvement with consumers or patients, registered pharmacists, and other licensed health care practitioners such as physicians, dentists and nurses
under the supervision of a certified or faculty preceptor. Not more than 45 hours of Board-accredited experience shall be acquired per week.

(e) Credit for college externships or other experience programs shall not be allowed for experience gained prior to the fifth college year (or third professional year) in the college of pharmacy program.

(f) The pharmacy college shall certify that the requirements of (b) above have been met. The Board shall provide appropriate forms for such certification.

13:39-8.5 Change in intern status

(a) A pharmacy intern applying for registration as a pharmacist in the State of New Jersey shall notify the Board within 10 days of any change in:

1. Beginning of a term of internship;

2. Termination of an internship;

3. Number of hours of employment;

4. Scheduled hours of employment;

5. Certified preceptor; and/or

6. Employing pharmacy.

13:39-8.6 Committee on Pharmacy Internship and Externship

(a) A Committee on Pharmacy Internship and Externship shall be established which shall consist of:

1. Two members of the Board of Pharmacy;

2. Two faculty members of the College of Pharmacy of Rutgers, the State University of New Jersey;

3. Two fifth or sixth year pharmacy students from the College of Pharmacy of Rutgers, the State University of New Jersey; and

4. Four approved pharmacy certified preceptors, one of whom shall be a practicing pharmacist in an independent pharmacy, one of whom shall be a practicing pharmacist in a chain pharmacy, one of whom shall be a practicing pharmacist in an institution, and one of whom shall be a registered pharmacist whose primary employment is in the pharmaceutical manufacturing industry.

(b) The Committee is established to advise and assist the Board in all matters relating to the pharmacy internship/externship program.

(c) The President of the Board shall designate a member of the Board to be the chairperson of the Committee.

13:39-8.7 Pharmacist intern log

(a) Pharmacist interns shall maintain a log for the internship period which meets the following requirements:

1. The log shall consist of an 8 by 11 inch looseleaf notebook.

2. Entries shall be made in the log weekly and shall contain:

i. The total number of prescriptions or medication orders filled in the pharmacy and the number filled by the intern;

ii. A brief summary of all new prescription drug products (new generic entities only) dispensed, such as physical-chemical characteristics, dosage, forms, and usage;

iii. Three examples of each of the following professional responsibilities:

(1) The use of the patient profile record requiring contact with patient, prescriber or hospital to resolve potential problems;

(2) Consultation with the patient or prescriber concerning special instructions regarding the use of medications;

(3) In a retail setting, consultation with the patient concerning over the counter medication;

iv. The certified preceptor's report;

v. Any atypical prescriptions compounded;

vi. Any change in status of any over the counter product;

vii. Any revision or addition in any Federal law or regulation or in New Jersey law or regulation concerning the practice of pharmacy;

viii. Any products or particular compounds removed from the market; and

ix. Any changes in product formulation.

(b) The log shall be submitted to the Board at the completion of the internship period.

SUBCHAPTER 9. PHARMACEUTICAL SERVICES WITHIN HEALTH CARE FACILITIES

13:39-9.1 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Drug administration'' means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

"Formulary'' means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

"Health care facility'' means a place where patients and/or residents are cared for under a common roof such as hospitals, long term care facilities, and establishments similar to those delineated in N.J.S.A. 45:14-32.

"Health care system'' means one or more health care facilities which are owned or controlled by the same legal entity.

"Institutional pharmacy'' means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. "Institutional pharmacy'' includes any areas of the health care facility or the health care system where pharmaceuticals are
stored, compounded or dispensed.

"Medication order'' means a written request for medication originated by an authorized prescriber and intended for patient use in the health care facility, and not for use of the institution's employees or their dependents or outpatients of the facility's clinics. A valid medication order contains the date ordered, the patient's name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the prescriber's electronic signature or password will meet legal requirements for a prescriber's original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each electronic signature or password and which prohibit their improper or unauthorized use.

"Pharmacy and Therapeutics Committee'' means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical and pharmacy staff and which acts to review and promote rational drug therapy and utilization in the facility. Its organization and function are described under N.J.A.C. 13:39-9.20.

"Unit dose drug distribution system'' means a system of dispensing drugs to be administered to patients of the facility whereby the medications are delivered daily (or more frequently) by the pharmacy to the patient care units in amounts equal to a 24-hour supply or less and are prepared, whenever possible, in single unit use packaging.

"Unit use packaging'' means a single unit use medication provided in sealed packaging which contains the following information for each dose:

1. Product name;

2. Strength;

3. Lot number;

4. Beyond use date; and

5. Manufacturer or repackager.

13:39-9.2 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.1 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility's pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

(b) An institutional pharmacy that is part of a health care system may fill medication orders for health care facilities that are part of the health care system and that provide pharmaceutical services directly to the patients of the health care system.

13:39-9.3 Control of institutional pharmaceutical services

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the registered pharmacist-in-charge.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the institution, it may enter into an agreement with a pharmacy licensed by the Board. The registered pharmacist-in-charge of that pharmacy and the designated pharmacist of the institution, if appropriate, shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

13:39-9.4 Pharmaceutical services

The pharmaceutical services shall be provided in accordance with accepted professional principles and standards and appropriate Federal, State and local laws. These services shall be responsive to the medication needs of the patient.

13:39-9.5 Pharmaceuticals

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. In such a case, the purchase shall be approved by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) Drugs approved by the Pharmacy and Therapeutics Committee for use in the facility shall be of an amount sufficient to compound or dispense all medication orders and prescriptions which may reasonably be expected to be compounded or dispensed by the pharmacist.

(c) The institutional pharmacy shall have an adequate inventory of drugs and biologicals to assure timely initiation of routine, emergency and disaster drug therapy;

(d) The storage and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of these drugs shall not be construed to be a violation of N.J.A.C. 13:39-5.4. A facility participating in experimental research involving residents must be in compliance with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research.

(e) The pharmacist-in-charge shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service of the facility. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by supportive personnel and co-signed by the supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, supportive personnel are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the hospital.

13:39-9.6 Drug disbursement; written orders; outpatient prescriptions

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or an electro-mechanical facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.9.

(b) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by the automatic stop order procedure or other methods in accordance with written policies of the facility.

(c) Orders involving abbreviations and chemical symbols shall be carried out only if the abbreviations and symbols are included on a standard list that has been approved by the medical staff.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use after consultation with the prescriber.

(e) Prescriptions written for employees of the institution or their dependents, or for outpatients of the facility's clinic, shall conform to the prescription requirements of N.J.S.A. 45:14-14.

13:39-9.7 Drug disbursement; oral orders

(a) The mandatory requirements of this section shall be implemented in accordance with the policy and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized prescriber. Such orders shall be immediately recorded and signed by the person receiving the order on the prescriber's order sheet or into the electronic data processing system.

(c) Oral orders for Schedule II controlled substances shall be permitted only in the case of a bona fide emergency situation.

(d) Oral orders shall be countersigned by the prescriber.

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), provided that the pharmacist:

1. Labels the medication for out-patient use pursuant to labelling requirements set forth in N.J.S.A. 45:14-24;

2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39-7.14; and

3. Ensures that discharge orders contain the attending physician's authorizations to release the remaining doses of the prescription to the patient or guardian.

13:39-9.8 Compounding

(a) Compounding of individual medication orders or prescriptions, the formulation of special drug needs and all bulk compounding (sterile or non-sterile) shall be done by or under the direct supervision of a pharmacist.

(b) Aseptic control procedures shall be maintained for the preparation of intravenous admixtures, the reconstitution of other sterile parenteral preparations, and the compounding and sterilization of other pharmaceutical products as needed.

(c) All prepackaging and labeling of drugs shall be done by or under the direct supervision of a pharmacist. Procedures shall be established for maintaining the integrity and manufacturer's control identity of prepackaged material. The prepackaging records shall be initialed by the supervising pharmacist.

13:39-9.9 Monitoring of patient drug therapy

(a) The pharmacist shall be responsible for monitoring drug therapy of patients in the facility. This shall include, but is not limited to, maintaining and reviewing the patient medication profile prior to the dispensing of medications.

(b) In instances involving the issuance and administration of STAT orders (orders requiring immediate attention) these drugs shall be documented on the patient's medication profile immediately after dispensing.

(c) When the pharmacy is closed, these drugs shall be documented on the patient's medication profile immediately after the pharmacy is reopened.

13:39-9.10 Medication not dispensed in finished form

The pharmacist shall be responsible for providing medication in a form that requires little or no further alterations, preparation, reconstitution, dilution or labeling by other licensed personnel. The pharmacist shall provide adequate instructions for those products that are not dispensed in finished form.

13:39-9.11 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice. Dispensing and labeling of outpatient prescriptions shall conform to N.J.S.A. 45:14-14.

13:39-9.12 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy and except as provided by written policies and procedures developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(b) Although the use of patient's own medications may be warranted in certain situations, it should be discouraged as a general or routine practice. If a patient's previously acquired medication is to be used, a written order to this effect shall be signed and dated by the patient's physician. Such medications shall be identified by the pharmacist as to contents and dispensing origin. Also, these medications shall be documented as part of the pharmacy's patient profile record system.

13:39-9.13 Investigational drugs; removal of outdated and recalled drugs; emergency drug supply; controlled dangerous substances

(a) Investigational drugs shall be properly labeled and stored in the pharmacy until dispensed. Essential information on the investigational drug shall be maintained in the pharmacy. The investigational drug may be administered only after basic chemical, pharmaceutical and pharmacological information has been made available to all concerned and all the requirements of the Food and Drug Administration and the facility are satisfied.

(b) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The registered pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

(c) Limited quantities of emergency drugs shall be placed under controlled conditions in locations within the facility to assure immediate access by authorized licensed health care personnel for use in an emergency situation. Written policies and procedures for the maintenance, content, control and accountability of emergency drugs supplied and located throughout the facility shall be developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(d) Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations. Written policies and procedures concerning control, use and accountability of controlled drugs shall be developed by the registered pharmacist-in-charge.

13:39-9.14 Drug-dispensing devices

(a) Where the use of a drug-dispensing device is approved as an integral part of the drug distribution system by the facility, the registered pharmacist-in-charge and the Pharmacy and Therapeutics Committee, the device may be used when the pharmacist is not on duty (absent during either the day or night), provided that any absence of the pharmacist does not exceed 24 hours, or when the pharmacist is on duty, provided that proper review of the use of the drug-dispensing device can be ascertained. The supervision of any drug dispensing device so utilized shall be the responsibility of the registered pharmacist-in-charge servicing the health care facility. The drug-dispensing device data shall be checked for accuracy every 24 hours by a pharmacist and so documented.

(b) Packaging and labeling of medication for drug-dispensing devices, when done in the facility, shall be performed under the direct supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the direct supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the direct supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the registered pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, physicians, authorized prescribers or designated pharmacy supportive personnel shall have access to the

medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f) All medications withdrawn from a drug dispensing device require a medication order by an authorized prescriber. All such medication orders shall be checked by the pharmacist within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

(g) When there is no licensed pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the registered pharmacist-in-charge who is responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

(h) The pharmacist shall be responsible for checking the drugs in the drug-dispensing devices at least monthly for expiration date, misbranding, physical integrity, security and accountability.

13:39-9.15 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the registered pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, control number or expiration date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2. If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed.

3. Any and all medication returned by out-patients of the facility shall not be redispensed.

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and cosigned and witnessed by a licensed nurse, physician or pharmacist and disposed of by the health care facility according to its written protocol.

13:39-9.16 Records and reports

(a) Records of the pharmaceutical services of the facility shall be the responsibility of the registered pharmacist-in-charge. These records shall be maintained and made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) The institutional pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39-7.14 and as follows:

1. The profile records for inpatients shall contain: the date of each entry; the name; sex; age or birthdate; location of the patient; the drug name, dose, route of administration and quantity dispensed; the initials of the pharmacist performing the dispensing or supervising; the reported diagnosis allergies and chronic condition(s) of the patient.

2. All notations made on the inpatients' profile records by supportive personnel shall be verified and countersigned by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored in a readily retrievable manner for five years following patient discharge.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall be signed or initialed by the dispensing pharmacist, dated, filed and kept for not less than five years from the last dispensing record date.

(d) Records for receipt, use and final disposition of controlled dangerous substances shall be maintained by the institutional pharmacy in compliance with the requirements of Federal and State controlled dangerous substances laws and regulations. Nursing administration and audit records for controlled dangerous substances shall be available for review by the pharmacy.

(e) Records of the receipt, dispensing and disposal of investigational drugs shall be maintained by the institutional pharmacy in compliance with Federal and State laws and regulations.

(f) The registered pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee.

13:39-9.17 Drug information and education

(a) The registered pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39-7.7.

(b) On each patient care unit, the pharmacist shall maintain the following:

1. A copy of the current institutional formulary;

2. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and

3. The telephone number of either the local or regional poison control center.

(c) The pharmacist shall participate in the drug education programs of the facility.

13:39-9.18 After hours access to the institutional pharmacy

(a) Only a pharmacist shall have access to the pharmacy stock of controlled dangerous substances in Schedules II through V.

(b) Only a pharmacist shall have access to the institutional pharmacy except that in a pharmacist's absence from an institution, a registered nurse designated by the registered pharmacist-in-charge may obtain medication from the hospital pharmacy as needed in an emergency and not available as floor stock.

(c) A designated registered nurse shall remove only those medication doses which shall be administered prior to the opening of the pharmacy. The designated registered nurse may remove the following from the pharmacy stock of drugs or automated dispensing device:

1. A drug in its original container or a drug pre-packaged by the pharmacy for use in the institution;

2. The required dose(s) of a drug from the original container for a specific patient.

(d) The registered pharmacist in charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;

2. The dosage size;

3. The amount taken;

4. The date;

5. The patient's name and location; and

6. The signature of the nurse.

(e) The registered pharmacist in charge shall obtain with the record in (d) above the container from which the required dose(s) was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be kept by the pharmacy for one year.

13:39-9.19 Advisory committees

The registered pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

13:39-9.20 Pharmacy and Therapeutics Committee

In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

13:39-9.21 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided.

13:39-9.22 Pharmacist staff

(a) The institutional pharmacist staff shall include the following:

1. A registered pharmacist-in-charge, who shall direct the institutional pharmacy service and be responsible to the administration of the facility;

2. Pharmacists who shall assist the registered pharmacist-in-charge as required depending on the size, scope and complexity of the service;

3. Any pharmacy interns, externs, and students, who shall function in accordance with the Board's rules and under certified preceptor(s) or faculty preceptor(s); and

4. Supportive and clerical personnel who shall work under the direct supervision and control of a registered pharmacist as provided in N.J.A.C. 13:39-6.4 and 6.7.

13:39-9.23 (Reserved)

13:39-9.24 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39-7.3 through 7.7.

(c) The space provided for the institutional pharmacy shall be in accord with the size of the facility and the scope and complexity of the pharmaceutical services.

13:39-9.25 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The registered pharmacist-in-charge shall be responsible for all the medications in the facility, that is, the drugs in the pharmacy service area, drugs in transit, and the drugs in the patient care areas.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the United States Pharmacopoeia/National Formulary.

5. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities must be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. Patient records shall be kept confidential.

13:39-9.26 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions. The equipment shall be sufficient to process drugs required by the facility.

13:39-9.27 Institutional decentralized pharmacies

(a) Institutional decentralized pharmacies, that is, "satellite pharmacies", means areas within the health care institution other than the original institutional permit location, where the preparation, dispensing, and compounding of medications are performed. Medication shall not be dispensed without a pharmacist present.

(b) Institutions utilizing or desiring to utilize institutional decentralized pharmacies shall file a remodeling application to the Board to conduct a decentralized pharmacy.

(c) Institutional decentralized pharmacies will be subject to normal Board inspections.

(d) The minimum equipment requirement for an institutional decentralized pharmacy shall be the following:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. Patient profile record system;

3. Properly safeguarded storage place if necessary for Schedule II controlled dangerous substances if not dispersed;

4. A refrigerator if necessary for the exclusive storage of biologicals and other medicinal products requiring refrigeration;

5. Labels; and

6. A sink with hot and cold running water exclusive of restroom facilities shall be easily accessible to institutional decentralized pharmacy personnel.

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39-10.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "Automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of

medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-7.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.14.

13:39-10.3 Authority to use automated medication system

(a) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

1. The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications, pursuant to N.J.S.A. 45:14-32, if an automated medication system is utilized at a location which does not have a pharmacy on-site, is responsible for the supervision of the operation of the system;

2. The Board has conducted an inspection of the pharmacy, including an inspection of the automated medication system;

3. The automated medication system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and

4. The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(b) The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications shall be responsible for the following:

1. Reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality and prevention of unauthorized access and malfunction;

2. Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability;

3. Assigning, discontinuing or changing personnel access to the automated medication system;

4. Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation; and

5. Ensuring compliance with all applicable provisions of N.J.A.C. 13:39.

13:39-10.4 Written policies and procedures of operation

(a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1. Include a table of contents;

2. Include a description of all procedures of operation;

3. Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least two years after the change is made. Each such change shall be signed or initialed by the registered pharmacist in charge and shall include the date on which the registered pharmacist in charge approved the change;

4. Set forth methods that shall ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

5. Set forth methods that shall ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39-7.14(h);

6. Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to licensed practitioners or qualified support personnel acting under the supervision of a registered pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

7. Identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a registered pharmacist.

(b) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

13:39-10.5 Personnel training requirements

The registered pharmacist in charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39-10.4.

13:39-10.6 Written program for quality assurance

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1. Requires continuous monitoring of the automated medication system;

2. Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every six months and whenever any upgrade or change is made to the system;

3. Establishes a protocol for measuring the effectiveness of the automated medication system;

4. Requires the pharmacy to report to the Board each recurring error of the automated medication system. A "recurring error," for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and

5. Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39-10.7 Written plan for recovery

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1. Planning and preparation for a disaster;

2. Procedures for response to a disaster;

3. Procedures for the maintenance and testing of the written plan for recovery; and

4. A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39-10.8 Written program for preventative maintenance of automated medication system

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

SUBCHAPTER 11. STERILE ADMIXTURE SERVICES IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11.1 Purpose and scope

This subchapter shall apply to all retail and institutional pharmacies which, on or after June 15, 1998, compound and dispense sterile admixture products.

13:39-11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

"Class 100 air quality conditions" means conditions in which the air particle count is no greater than a total of 100 particles of 0.5 micrometers and larger per cubic foot of air.

"Class 1,000 air quality conditions" means conditions in which the air particle count is no greater than a total of 1,000 particles of 0.5 micrometers and larger per cubic foot of air.

"Class 10,000 air quality conditions'' means conditions in which the air particle count is no greater than a total of 10,000 particles of 0.5 micrometers and larger per cubic foot of air.

"Clean room'' means an enclosed space in which the concentration of airborne particles is controlled and there are one or more "clean zones.''

"Clean zone'' means a defined space in which the concentration of airborne particles is controlled to meet a specified airborne-particulate cleanliness class.

"Controlled environment'' means a designated area for sterile product preparation.

13:39-11.3 Sterile admixture services; environment

A sterile admixture service is one specializing in the compounding and dispensing of sterile products upon receipt of a valid prescription or medication order. Such compounding shall take place in the confines of a controlled environment as required by N.J.A.C. 13:39-11.17; or when circumstances permit as set forth in N.J.A.C. 13:39-11.12(c), in a laminar hood, as provided by N.J.A.C. 13:39-11.23, or in a glove box, as provided by N.J.A.C. 13:39-11.24.

13:39-11.4 Compliance

(a) A retail pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 or applies to compound and dispense sterile admixture products commencing after June 15, 1998 shall meet the requirements of this subchapter subject to the following exception:

1. A retail pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 shall meet the requirements of N.J.A.C. 13:39-11.17(b)4 and 11.18(g) by December 15, 1999. Individual pharmacies may request additional time by making application to the Board and demonstrating significant hardship or other good cause.

(b) An institutional pharmacy which compounds and dispenses sterile admixture products as of June 15, 1998 shall meet the requirements of this subchapter by December 15, 1999. Individual pharmacies may request additional time by making application to the Board and demonstrating significant hardship or other good cause.

(c) An institutional pharmacy which applies to the Board for an approval to compound and dispense sterile admixture products commencing after June 15, 1998 shall meet the requirements of this subchapter.

13:39-11.5 General requirement

An applicant or permitholder who wishes to prepare sterile admixtures shall notify the Board at least 30 days prior to commencement of preparation of any sterile admixture products, and must receive approval from the Board before commencing sterile admixture preparation.

13:39-11.6 Pharmacist in charge and permitholders' responsibilities

(a) That section of a pharmacy which provides a sterile admixture service shall be under the direct supervision of a pharmacist licensed to practice in this State.

(b) The pharmacist in charge shall have the responsibility, in that section of the pharmacy which provides this special service for, at a minimum, the following:

1. Preparation of sterile admixtures compounded within the pharmacy or pharmacy satellite;

2. Storage of all materials pertinent to the preparation of sterile admixtures, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials;

3. Labeling of all containers of sterile admixture preparations compounded with the pharmacy;

4. Recording all transactions of the pharmacy as may be applicable to State, Federal and local laws and rules, as may be necessary to maintain accurate control over, and accountability for, all pharmaceutical materials; and

5. Ensuring that only licensed pharmacists meeting the requirements of (a) above, or supportive personnel under direct supervision of an IV trained licensed pharmacist as defined in N.J.A.C. 13:39-11.8(a), prepare, compound and dispense the sterile admixture preparations.

13:39-11.7 Training requirements

(a) The pharmacist in charge and all personnel involved in sterile admixture preparation shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile products and annually thereafter. That documentation shall be maintained by the permitholder for five years and made available to the Board upon request.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to performing delegated sterile admixture services, all supportive personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to sterile admixture services as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39-11.14;

2. Familiarity with the necessary compounding techniques; and

3. Appropriate aseptic technique, which shall be proven by means of a test batch of culture media, media fill or the equivalent.

(c) At least annually, the pharmacist in charge shall be responsible for testing the aseptic technique of all personnel involved in sterile product preparation by means of a test batch of culture media, media fill or the equivalent. Test results shall be maintained for five years, and shall be made available for the Board's inspection upon request. Individuals who fail to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile product preparation until demonstrating acceptable technique by means of a test batch of culture media, media fill or the equivalent.

13:39-11.8 Supportive personnel; required supervision

(a) Dispensing pharmacists shall provide direct supervision to supportive personnel who are performing delegated sterile admixture tasks. The ratio of dispensing pharmacists to supportive personnel shall not exceed 1:2 at any given time.

1. For the purpose of this subchapter, "direct supervision'' means that the dispensing pharmacist shall be present in the pharmacy dispensing area whenever supportive personnel are compounding sterile admixture products, and shall conduct checks of all steps in preparation, compounding and dispensing of sterile admixture products.

2. Supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

(b) The dispensing pharmacist may delegate to supportive personnel only the following tasks: recording of the prescription, selection of the drugs, container and diluent, typing of labels and compounding of the sterile admixture. The dispensing pharmacist shall ensure that each task has been performed correctly in the dispensing process.

13:39-11.9 Batch preparation

Pharmacists and supportive personnel may prepare sterile products consistent with the provisions of N.J.A.C. 13:39-11.8 in a quantity that is supported by prior valid prescription orders before receiving a valid written prescription or medication order, provided the pharmacist can document a history of valid prescriptions subsequently received shortly thereafter or medication orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship, and provided they maintain the prescription on file for all such products dispensed at the pharmacy as
required by state law. The pharmacist shall document the batch preparation process in accordance with N.J.A.C. 13:39-11.10(e).

13:39-11.10 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39-11.6, the dispensing pharmacist shall ensure that the sterile admixture product has been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (e) below are documented and that the pharmacist responsible for each preparation can be identified.

(c) The retail dispensing pharmacist shall be responsible for completing a form which documents the completion of each of the steps of the compounding process in (e) below. The tracking document(s) shall be initialed by the individual(s) who completed each step.

(d) The institutional dispensing pharmacist shall assure that appropriate documentation is maintained to track completion of the steps of the compounding process set out in (e) below.

(e) Compounding steps which shall be documented are as follows:

1. Receipt of prescription;

2. Recording of prescription in the patient record profile system, pursuant to N.J.A.C. 13:39-11.16;

3. Correct selection of the drugs, container, and diluent prior to their being compounded;

4. Verification that all pharmacy sterile admixture compounding is performed within a class 100 laminar air flow hood or class 100 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;

5. Verification that residual components comply with the prescription;

6. Verification that the prescription label complies with the requirements of N.J.A.C. 13:39-11.11; and

7. Verification that the prescription is complete and ready to be dispensed, including any necessary ancillary supplies.

(f) The completed documentation shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of a record must be retrievable within 24 hours.

13:39-11.11 Information required to appear on prescription label

(a) The dispensed container for any sterile admixture product shall bear a permanently affixed label with at least the following information:

1. The date and time prepared;

2. In the retail pharmacy only, the name of the prescriber;

3. The name of the patient;

4. Directions for use;

5. The name of the base solution;

6. The name and quantity of drug(s) added;

7. The name or identifying code of the pharmacist who checked or prepared the sterile admixture product;

8. The name, address, and telephone number of the pharmacy;

9. The pharmacy's Drug Enforcement Administration (DEA) number, if the sterile admixture product contains any controlled dangerous substances;

10. The expiration date and time of the sterile admixture product (If no time is stated, it is presumed to be 11:59 P.M. of the stated expiration date);

11. Any ancillary and cautionary instructions as needed;

12. As pertinent, a warning consistent with applicable Federal and State law that cytotoxic products are biohazardous; and

13. As pertinent, the requirements for proper storage.

13:39-11.12 Expiration date of sterile preparation

(a) The expiration date of a sterile admixture product shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation.

(b) Any expiration date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board.

(c) In an institutional pharmacy, any sterile admixture product which is prepared under the pharmacy's control in a class 100 laminar air flow hood which is in an environment which meets the requirements of N.J.A.C. 13:39-11.23, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a product is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the product shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a class 100 laminar air flow hood.

13:39-11.13 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded sterile preparations for delivery from the pharmacy to the patient in order to assure and maintain sterility and stability of these preparations. To ensure the integrity and efficacy of compounded sterile admixture products, the pharmacist in charge shall ensure that:

1. A reasonable effort is made to provide tamper-evident packing;

2. Retail delivery is made from the pharmacy to the patient within a reasonable time; and

3. Proper in-transit storage is provided consistent with product labeling.

13:39-11.14 Policy and procedure manual

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to sterile admixture services.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. A risk-management program (including, but not limited to, incident report procedures, an adverse drug reaction system, and a product contamination system);

2. Security measures ensuring that the premises where sterile admixture drugs are present are secured, so as to prevent access by unauthorized personnel;

3. Equipment;

i. Procedures for use; and

ii. Documentation of appropriate certifications;

4. Sanitation standards and procedures;

5. Reference materials as set out in N.J.A.C. 13:39-7.7 and 11.25;

6. Information concerning drug:

i. Preparation;

ii. Storage and handling;

iii. Dispensing;

iv. Labeling;

v. Delivery; and

vi. Destruction, recalls and returns;

7. Patient recordkeeping as set forth in N.J.A.C. 13:39-11.16;

8. Handling, dispensing and documentation of investigational new drugs;

9. A quality assurance program as set forth in N.J.A.C. 13:39-11.15;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39-11.7;

11. Compounding process validation;

12. Documentation as set forth in N.J.A.C. 13:39-11.10;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients);

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hoods; and

18. Written procedures in compliance with the Occupational Safety and Health Administration standards for handling small and large spills of antineoplastic agents and other hazardous substances.

(c) The pharmacist in charge shall review and, if necessary, amend the policy and procedure manual on at least an annual basis. Documentation of the annual review shall be made available to the Board upon request.

13:39-11.15 Quality assurance program

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile admixture products, which, prior to dispensing, have been in any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as "compounded'').

(b) The dispensing pharmacist shall ensure that the sterile admixture product retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that sterile admixture products shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each sterile admixture product dispensed;

2. The quality assurance program encompasses all phases of sterile admixture product preparation, distribution, storage, administration, and directions for use for each type of product dispensed;

3. All compounding processes representative of all types of manipulations, products and batches must be sterile tested and validated at least every 12 months.

4. Air and surface sampling for microbial organisms in class 100 laminar air flow hoods and class 1,000 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;

5. Laminar air flow hoods shall be certified every six months by an independent certification company;

6. The class 1,000 clean room and class 10,000 anteroom shall be certified every six months by an independent certification company; and

7. All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E-48.1 et seq., P.L. 1989, c.34).

13:39-11.16 Patient profile records

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39-7.14; and

2. All medication orders for institutional patients.

(b) The pharmacist in charge shall ensure that a reasonable, documented attempt is made to include in the record over-the-counter and home remedies used by noninstitutional patients.

(c) The pharmacist in charge shall ensure that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available.

13:39-11.17 Controlled environment: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile product preparation, known as the "controlled environment," consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39-11.23 or 11.24.

(b) A controlled environment shall be:

1. Accessible only to designated personnel;

2. Used only for the preparation of sterile products, or such other tasks that require a controlled environment;

3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and

4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit.

13:39-11.18 Controlled environment: construction

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the controlled environment shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.

(b) All surfaces shall be resistant to damage from sanitizing agents.

(c) Junctures where ceilings meet wall shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings which consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Solid walls shall consist either of panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have vinyl floor covering and shall be seamless or have heat-welded seams and coving to the sidewall.

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills). All sprinkler heads shall be flush with the ceiling.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and air tight.

(i) All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(j) Any clean room construction other than that specified in (a) through (i) above (for example, softwall, prefabricated, modular, portable clean rooms) shall be approved by the Board prior to installation and use.

13:39-11.19 Controlled environment: stocking, maintenance and supplies

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods which are required for the tasks to be performed there;

2. Items which are nonpermeable, nonshedding, and resistant to disinfectants; and

3. Items which have been cleaned and sanitized immediately prior to their being placed in the clean room.

(b) Whenever possible, equipment and other items used in the controlled environment should not be taken from these rooms except for calibration, servicing, or other activity associated with the proper maintenance of the item.

(c) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(d) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(e) The controlled environment area shall contain the following supplies:

1. Gloves, masks, gowns, and other personal protective equipment;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Hand-washing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

13:39-11.20 Controlled environment: clean room

(a) The clean room shall contain no sinks or floor drains.

(b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized.

(c) The clean room shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(d) Appropriate environmental control devices capable of maintaining class 1,000 air-quality conditions during normal activity shall be in place.

(e) The clean room shall contain the following equipment:

1. A laminar airflow hood or suitable HEPA filter system;

2. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and

3. Ancillary supplies required for proper compounding.

13:39-11.21 Controlled environment: anteroom

(a) The anteroom shall have an air quality of Class 10,000 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Waste containers for all personal protective equipment;

3. An eyewash station; and

4. A hazardous waste spill kit.

(c) A refrigerator, as required by United States Pharmacopoeia Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the sterile admixture product, but shall not be located within the controlled environment.

13:39-11.22 Vertical air laminar flow hoods

(a) Pharmacies shall compound antineoplastic agents and other hazardous substances in a class 100 vertical air laminar flow hood.

(b) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to OSHA Work Practice Guidelines, as set forth in CPL 2-2.20B CH-4, Chapter 21, incorporated herein by reference, as amended and supplemented.

13:39-11.23 Laminar air flow hoods not in a clean room

Institutional pharmacy class 100 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

13:39-11.24 Controlled environment: self-contained sterile glove boxes

Self-contained class 10 to class 100 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

13:39-11.25 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39-7.7, each sterile admixture service shall contain recognized references pertinent to specialized sterile admixture practice.

13:39-11.26 Disposal of drugs and materials

All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, shall be disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E-48.1 et seq., P.L. 1989, c.34), so as not to endanger the public health.

13:39-11.27 Security

The sterile admixture area and its contents and other areas where sterile admixture drugs are present shall be secured, so as to prevent access by unauthorized personnel.

SUBCHAPTER 12. NUCLEAR PHARMACIES

13:39-12.1 Definitions

The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

“Authentication of product history’’ includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

“Authorized practitioner’’ means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

"Designated agent'' means an individual under the direct supervision of a practitioner authorized to communicate the practitioner's instructions to the nuclear pharmacy.

"Direct supervision'' means that a qualified nuclear pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing of drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Internal test assessment'' includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

"Radiopharmaceutical'' means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

"Radiopharmaceutical quality assurance'' includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

"Radiopharmaceutical service'' includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the direct supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal United States Nuclear Regulatory Commission or its successor's requirements and the requirements established by the State of New Jersey Bureau of Radiation Protection. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy dispensing radioactive drugs may be exempted from the general space requirements for pharmacies.

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. The environment where the handling of radioactive materials takes place shall be properly ventilated so that radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;

2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas; and

3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) The immediate outer container of a radioactive drug to be dispensed shall be labeled with the following:

1. The standard radiation symbol;

2. The words, “CAUTIONÖRADIOACTIVE MATERIAL’’;

3. The radionuclide;

4. The chemical form;

5. The amount of radioactive material contained in millicuries or microcuries;

6. If a liquid, the volume in milliliters;

7. The requested calibration time for the radioactivity contained;

8. The name, address, and telephone number of the nuclear pharmacy;

9. The prescription number; and

10. The date and patient’s name, if available.

(f) The immediate container shall be labeled with the following:

1. The standard radiation symbol;

2. The words, “CAUTIONÖRADIOACTIVE MATERIAL’’;

3. The name of the radiopharmaceutical.

(g) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(h) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission or its successor. A nuclear pharmacy may furnish radiopharmaceuticals to these practitioners for patient use.

(i) Nuclear pharmacies shall comply with all applicable laws and regulations of Federal and State agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive rules pertaining to pharmacy permits for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(j) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(k) Prescription orders for delivery of radioactive drugs for use in the medical practice of a United States Nuclear Regulatory Commission licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(l) A qualified nuclear pharmacist shall have the authority to delegate to any qualified and properly trained person or persons, acting under his or her direct supervision, any nuclear pharmacy act which a reasonable and prudent pharmacist would find is within the scope of sound pharmaceutical judgment to delegate. Such delegation may only occur if, in the professional opinion of the qualified nuclear pharmacist, the act may be properly and safely performed by the person to whom the pharmacy act is delegated. The delegated act may only be performed in its customary manner, not in violation of other statutes. The person to whom a nuclear pharmacy act is delegated shall not hold himself or herself out to the public as being authorized to practice pharmacy.

13:39-12.3 General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall meet the following requirements:

1. He or she is a pharmacist licensed to practice in the State of New Jersey; and

2. He or she meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

13:39-12.4 Minimum requirements for space, equipment, supplies, and library

(a) Each nuclear pharmacy must meet the following requirements for space:

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for non-radioactive drugs;

2. Hot lab and storage area shall be a minimum of 120 square feet; and

3. The compounding and dispensing area shall be a minimum of 300 square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

1. Dose calibrator;

2. Refrigerator;

3. Drawing station;

4. Well scintillation counter;

5. Microscope;

6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;

7. Radiation survey equipment of the appropriate type and calibration to detect quantities of radioactive materials as prescribed in the appropriate radioactive material licenses; and

8. Other equipment deemed necessary for radiopharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

(c) Each nuclear pharmacy shall have on the premises the following, up-to-date reference books:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. State statutes and rules relating to pharmacy;

3. State and Federal regulations governing the use of applicable radioactive materials; and

4. Text relating to the practice of nuclear pharmacy and radiation safety.

13:39-12.5 Quality control

The holder of a nuclear pharmacy permit shall be responsible for the radioactive quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biological and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in humans and other animals, including internal test assessment and authentication of product history.

CHAPTER 45C
UNIFORM REGULATIONS

SUBCHAPTER 1. LICENSEE DUTY TO COOPERATE AND TO COMPLY WITH BOARD ORDERS

13:45C-1.1 Applicability, scope and definitions

(a) This subchapter shall apply to all licensees of any board, committee or sub-unit within the Division of Consumer Affairs.

(b) For the purpose of this subchapter, "licensee'' shall mean any licensee, permittee, certificate holder or registrant of:

1. The Division of Consumer Affairs;

2. Any professional or occupational licensing board within the Office of Professional/Occupational Boards and any committee, or other subunit of a board or committee located within the Division;

3. The Office of Consumer Protection; or

4. The Legalized Games of Chance Control Commission.

13:45C-1.2 Licensee's duty to cooperate in investigative inquiries

(a) A licensee shall cooperate in any inquiry, inspection or investigation conducted by, or on behalf of, a board, the Director or the licensee's licensing agency into a licensee's conduct, fitness or capacity to engage in a licensed profession or occupation where said inquiry is intended to evaluate such conduct, fitness or capacity for compliance with applicable statutory or regulatory provisions.

(b) A licensee's failure to cooperate, absent good cause or bona fide claim of a privilege not identified in N.J.A.C. 13:45C-1.5 as unavailable, may be deemed by the board, the Director, or the licensing agency to constitute professional or occupational misconduct within the meaning of N.J.S.A. 45:1-21(e) or the agency's enabling act and thus subject a licensee to disciplinary action pursuant to N.J.S.A. 45:1-21(h) or the agency's enabling act.

13:45C-1.3 Specific conduct deemed failure to cooperate

(a) The following conduct by a licensee may be deemed a failure to cooperate and, therefore, professional or occupational misconduct and grounds for suspension or revocation of licensure:

1. The failure to timely respond to an inquiry to provide information in response to a complaint received concerning licensee conduct;

2. The failure to timely provide records related to licensee conduct;

3. The failure to attend any scheduled proceeding at which the licensee's appearance is directed. In the event that a licensee elects to retain counsel for the purpose of representation in any such proceeding, it shall be the licensee's responsibility to do so in a timely fashion. The failure of a licensee to retain counsel, absent a showing of good cause therefor, shall not cause an adjournment of the proceeding;

4. The failure to timely respond or to provide information requested pursuant to a demand under N.J.S.A. 45:1-18 or other applicable law or to provide access to any premises from which a licensed profession or occupation is conducted. Included within this paragraph shall be the failure to respond to any demand for statement or report under oath, the failure to permit the examination of any goods, ware or item used in the rendition of the professional or occupational service and the failure to grant access to records, books or other documents utilized in the practice of the occupation or profession;

5. The failure to answer any question pertinent to inquiry made pursuant to N.J.S.A. 45:1-18 or other applicable law unless the response to said question is subject to a bona fide claim of privilege;

6. The failure to make proper and timely response by way of appearance or production of documents to any subpoena issued pursuant to N.J.S.A. 45:1-18 or as may otherwise be provided by law; or

7. The failure to provide to the Board, the Director or the licensing agency timely notice of any change of address from that which appears on the licensee's most recent license renewal or application.

13:45C-1.4 Failure to comply with Board orders as professional or occupational misconduct

The failure of a licensee to comply with an order duly entered and served upon the licensee or of which the licensee has knowledge shall be deemed professional or occupational misconduct.

13:45C-1.5 Unavailability of privileges in investigative or disciplinary proceedings

(a) In any investigative inquiry conducted pursuant to N.J.S.A. 45:1-18 or in any disciplinary proceeding conducted pursuant to N.J.S.A. 45:1-21, or as may otherwise be authorized by law, the physician-patient privilege, psychologist-patient privilege, marriage and family therapist-client privilege, professional counselor-client privilege, associate counselor-client privilege, social worker-client privilege and the alcohol and drug counselor-client privilege shall be unavailable.

(b) Any statements or records otherwise subject to a claim of the stated privileges which may be obtained by the Board, its agent or the Attorney General pursuant to N.J.S.A. 45:1-18 shall remain confidential and shall not be disclosed unless so ordered by a court of competent jurisdiction, the appropriate licensing board or the Office of Administrative Law in a contested case.

13:45C-1.6 Maintenance of and access to statements, records or other information that is subject to a privilege declared unavailable

(a) Any statements, records or other information which may be subject to any privilege declared unavailable in this subchapter shall be maintained in a secure place and manner by:

1. The evidence custodian within the Division of Consumer Affairs, Enforcement Bureau;

2. The professional or occupational licensing board and the committee or other subunit of a board or committee located within the Division which has a direct connection with, or a need for access to, the matter to which the statements, records or other information pertain; or

3. A Deputy Attorney General.

(b) Except as may be otherwise ordered as provided in the subchapter, access to statements, records or other information shall be afforded only to employees of the Attorney General, the Enforcement Bureau, or the Board or other subunit of the Division having a direct connection with, or a need for access to, the matter to which the statement, records or other information pertain.

(c) The statements, records or other information shall be retained only for the period of time during which an investigation remains open or until the completion of all administrative or judicial proceedings relating thereto, at which time they shall be returned to the licensee or other person from whom they were obtained. In the absence of such licensee or other person, the statements, records or other information shall be returned to the patient, where appropriate.